BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

As rescanning documents *will not* correct images, please do not report the images to the Image Problem Mailbox.

Thus, this case is, for all practical purposes, exactly the case that the majority seeks to distinguish, i.e. a reversal by this court followed by a new ground of denial by the PTO.

I would, therefore, address on the merits the new ground for denying registration raised by the PTO, which is "lack of ownership" by the appellant. There is no assertion by appellant that the PTO's denial of registration on that basis was not made in accord with proper procedure or is otherwise unfair. Indeed, appellant conceded at oral argument that the PTO had the authority to use that basis of denial, even after the earlier opinion of this court.

On the merits, the PTO determined that Wella U.S., a subsidiary of Wella A.G., is the owner of the WELLASTRATE mark sought to be registered and that only the owner may register a trademark. 15 U.S.C. § 1051 (1982). This finding of the PTO, however, is clearly erroneous.

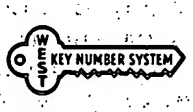
The Board based its finding that Wella A.G. does not own the mark on the fact that Wella U.S. had previously registered four separate marks in the Wella family. The Board referred to 15 U.S.C. § 1057(b), which states:

> A certificate of registration of a mark upon the principal register provided by this chapter shall be prima facie evidence of the validity of the mark, and of registrant's exclusive right to use the mark in commerce in connection with the goods or services specified in the certificate, subject to any conditions and limitations stated therein.

Although the Board may have been correct in drawing a presumption based on that section and the ownership by Wella U.S. of its four registered marks that it and not Wella, A.G. owned the mark at issue, I believe it is clear that this presumption was overcome by the declaration of Wella, A.G., supported by the foreign registration, that it owned a fifth mark—WELLASTRATE—at issue here.

Included in Wella A.G.'s application for registration of WELLASTRATE is a declaration by the President of Wella A.G. that he "believes said corporation to be the owner of the trademark sought to be registered." Also included is a copy of the 1958 registration of the same mark by Wella A.G. in the Federal Republic of Germany. No evidence was presented by the PTO to contradict that evidence of ownership by Wella A.G.

For the foregoing reasons, the Board's rejection on the basis of "lack of ownership" should be reversed.



In re Jack R. WANDS, Vincent R. Zurawski, Jr., and Hubert J.P. Schoemaker.

No. 87-1454.

United States Court of Appeals, Federal Circuit.

Sept. 30, 1988.

Inventors of method to create immunoassay of hepatitis B surface antigen using monoclonal antibodies sought patent. The Board of Patent Appeals and Interferences denied the patent on grounds it was not enabling. On appeal, the Court of Appeals, Edward S. Smith, Circuit Judge, held that: (1) determination of enablement is reviewed as question of law; (2) while deposit of living cells can be used to satisfy enabling requirement, it is not necessary; (3) undue experimentation was not necessary to produce art for method of immunoassay of hepatitis B surface antigen using monoclonal antibodies; and (4) enablement of patent involving living microorganisms is not precluded by necessity of some experiments such as routine screening.

Reversed.

Pauline Newman, Circuit Judge, concurred in part and dissented in part with opinion.

1. Patents ⇐113(6)

While facts underlying patent application as found by Board of Patent Appeals and Interferences are reviewed under clearly erroneous standard, enablement determination is reviewed as a question of law. 35 U.S.C.A. § 112.

2. Patents ⇐99

Where an invention depends on use of living materials such as microorganisms or cultured cells, it may be impossible to enable the public to make the invention solely by means of a written disclosure; thus, enabling requirement can be met by deposit of living materials in cell depositories which will distribute samples to public who wish to practice the invention after the patent issues. 35 U.S.C.A. § 112.

3. Patents ⇐99

Although inventions involving microorganisms or other living cells can be enabled by their deposit with cell depository, a deposit is not always necessary to satisfy the enablement requirement. 35 U.S.C.A. § 112.

4. Patents ⇐99

No deposit of living cells is necessary to meet the enabling requirement of invention which involves microorganisms or other living cells if the biological organism can be obtained from readily available sources or derived from readily available starting materials through routine screening that does not require undue experimentation. 35 U.S.C.A. § 112.

5. Patents ⇐99

Determination of whether specification in a patent application involving living cells is enabled without a deposit of cells is decided on facts of the particular case. 35 U.S.C.A. § 112.

6. Patents ⇐99

Undue experimentation was not necessary to practice art of method for immunoassay of hepatitis B surface antigen using monoclonal antibodies and thus invention was enabling without deposit of living cells; successful and successive creation of antibodies was not undermined by four prior failures or inventors' lack of testing of other stored hybridomas created by method where cell fusion was technique well known to those of ordinary skill in monoclonal antibody art, and no claim was made that fusion step was more difficult or unreliable for any other antigen than antigen created by method. 35 U.S.C.A. § 112.

7. Patents ⇐99

Enablement of patent involving living microorganisms is not precluded by necessity for some experimentation such as routine screening. 35 U.S.C.A. § 112.

8. Patents ⇐99

Determination of whether undue experimentation is needed to reproduce an invention involving living microorganisms and demonstrate lack of enablement is not a single factual determination but a conclusion reached by weighing many factual considerations. 35 U.S.C.A. § 112.

9. Patents ⇐99

Factors to be considered in determining whether a disclosure would require undue experimentation and undermine enabling requirement for patent involving living microorganisms due to lack of deposit of cells include quantity of experimentation necessary, amount of direction or guidance presented, presence or absence of working examples, nature of the invention, state of prior art, relative skill of those in the art, predictability of the art, and breadth of the claims. 35 U.S.C.A. § 112.

Jorge A. Goldstein, of Saidman, Sterne, Kessler & Goldstein, Washington, D.C., argued for appellant. With him on the brief was Henry N. Wixon, Washington, D.C.

John H. Raubitschek, Associate Sol., Com'r of Patents and Trademarks, of Arlington, Va., argued for appellee. With him on the brief were Joseph F. Nakamura, Sol. and Fred E. McKelvey, Deputy Sol., Washington, D.C.

Before SMITH, NEWMAN, and BISSELL, Circuit Judges.

EDWARD S. SMITH, Circuit Judge.

This appeal is from the decision of the Patent and Trademark Office (PTO) Board of Patent Appeals and Interferences (board) affirming the rejection of all remaining claims in appellant's application for a patent, serial No. 188,735, entitled "Immunoassay Utilizing Monoclonal High Affinity IgM Antibodies," which was filed September 19, 1980.[1] The rejection under 35 U.S.C. § 112, first paragraph, is based on the grounds that appellant's written specification would not enable a person skilled in the art to make the monoclonal antibodies that are needed to practice the claimed invention without undue experimentation. We reverse.

I. *Issue*

The only issue on appeal is whether the board erred, as a matter of law, by sustaining the examiner's rejection for lack of enablement under 35 U.S.C. § 112, first paragraph, of all remaining claims in appellants' patent application, serial No. 188,735.

II. *Background*

A. *The Art.*

The claimed invention involves immunoassay methods for the detection of hepatitis B surface antigen by using high-affinity monoclonal antibodies of the IgM isotype. *Antibodies* are a class of proteins (immunoglobulins) that help defend the body against invaders such as viruses and bacteria. An antibody has the potential to bind tightly to another molecule, which molecule is called an *antigen*. The body has the ability to make millions of different antibodies that bind to different antigens. However, it is only after exposure to an antigen that a complicated *immune response* leads to the production of antibodies against that antigen. For example, on the surface of hepatitis B virus particles there is a large protein called *hepatitis B surface antigen* (HBsAg). As its name implies, it is capable of serving as an antigen. During a hepatitis B infection (or when purified HBsAg is injected experimentally), the body begins to make antibodies that bind tightly and specifically to HBsAg. Such antibodies can be used as regents for sensitive diagnostic tests (*e.g.*, to detect hepatitis B virus in blood and other tissues, a purpose of the claimed invention). A method for detecting or measuring antigens by using antibodies as reagents is called an *immunoassay*.

Normally, many different antibodies are produced against each antigen. One reason for this diversity is that different antibodies are produced that bind to different regions (determinants) of a large antigen molecule such as HBsAg. In addition, different antibodies may be produced that bind to the same determinant. These usually differ in the tightness with which they bind to the determinant. *Affinity* is a quantitative measure of the strength of antibody-antigen binding. Usually an antibody with a higher affinity for an antigen will be more useful for immunological diagnostic tests than one with a lower affinity. Another source of heterogeneity is that there are several immunoglobulin classes or *isotypes*. Immunoglobulin G (IgG) is the most common isotype in serum. Another isotype, immunoglobulin M (IgM), is prominent early in the immune response. IgM molecules are larger than IgG molecules, and have 10 antigen-binding sites instead of the 2 that are present in IgG. Most immunoassay methods use IgG, but the claimed invention uses only IgM antibodies.

For commercial applications there are many disadvantages to using antibodies from serum. Serum contains a complex mixture of antibodies against the antigen of interest within a much larger pool of antibodies directed at other antigens. These are available only in a limited supply that ends when the donor dies. The goal of monoclonal antibody technology is to produce an unlimited supply of a single purified antibody.

The blood cells that make antibodies are *lymphocytes*. Each lymphocyte makes only one kind of antibody. During an immune response, lymphocytes exposed to

1. *In re Wands*, Appeal No. 673-76 (Bd.Pat.App. & Int. Dec. 30, 1986).

their particular antigen divide and mature. Each produces a *clone* of identical daughter cells, all of which secrete the same antibody. Clones of lymphocytes, all derived from a single lymphocyte, could provide a source of a single homogeneous antibody. However, lymphocytes do not survive for long outside of the body in cell culture.

Hybridoma technology provides a way to obtain large numbers of cells that all produce the same antibody. This method takes advantage of the properties of *myeloma* cells derived from a tumor of the immune system. The cancerous myeloma cells can divide indefinitely in vitro. They also have the potential ability to secrete antibodies. By appropriate experimental manipulations, a myeloma cell can be made to fuse with a lymphocyte to produce a single hybrid cell (hence, a hybridoma) that contains the genetic material of both cells. The hybridoma secretes the same antibody that was made by its parent lymphocyte, but acquires the capability of the myeloma cell to divide and grow indefinitely in cell culture. Antibodies produced by a clone of hybridoma cells (i.e., by hybridoma cells that are all progeny of a single cell) are called monoclonal antibodies.[2]

B. *The Claimed Invention.*

The claimed invention involves methods for the immunoassay of HBsAg by using high-affinity monoclonal IgM antibodies. Jack R. Wands and Vincent R. Zurawski, Jr., two of the three coinventors of the present application, disclosed methods for producing monoclonal antibodies against HBsAg in United States patent No. 4,271,145 (the '145 patent), entitled "Process for Producing Antibodies to Hepatitis Virus and Cell Lines Therefor," which patent issued on June 2, 1981. The '145 patent is incorporated by reference into the application on appeal. The specification of the '145 patent teaches a procedure for immunizing mice against HBsAg, and the use of lymphocytes from these mice to produce hybridomas that secrete monoclonal antibodies specific for HBsAg. The '145 patent discloses that this procedure yields both IgG and IgM antibodies with high-affinity binding to HBsAg. For the stated purpose of complying with the best mode requirement of 35 U.S.C. § 112, first paragraph, a hybridoma cell line that secretes IgM antibodies against HBsAg (the 1F8 cell line) was deposited at the American Type Culture Collection, a recognized cell depository, and became available to the public when the '145 patent issued.

The application on appeal claims methods for immunoassay of HBsAg using monoclonal antibodies such as those described in the '145 patent. Most immunoassay methods have used monoclonal antibodies of the IgG isotype. IgM antibodies were disfavored in the prior art because of their sensitivity to reducing agents and their tendency to self-aggregate and precipitate. Appellants found that their monoclonal IgM antibodies could be used for immunoassay of HbsAg with unexpectedly high sensitivity and specificity. Claims 1, 3, 7, 8, 14, and 15 are drawn to methods for the immunoassay of HBsAg using high-affinity IgM monoclonal antibodies. Claims 19 and 25–27 are for chemically modified (*e.g.*, radioactively labeled) monoclonal IgM antibodies used in the assays. The broadest method claim reads:

> 1. An immunoassay method utilizing an antibody to assay for a substance comprising hepatitis B-surface antigen (HBsAg) determinants which comprises the steps of:
>
> contacting a test sample containing said substance comprising HBsAg determinants with said antibody; and
>
> determining the presence of said substance in said sample;
>
> wherein said antibody is a monoclonal high affinity IgM antibody having a binding affinity constant for said HBsAg determinants of at least 10^9 M^{-1}.

Certain claims were rejected under 35 U.S.C. § 103; these rejections have not

2. For a concise description of monoclonal antibodies and their use in immunoassay see *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1368–71, 231 USPQ 81, 82–83 (Fed. Cir.1986), *cert. denied*, — U.S. —, 107 S.Ct. 1606, 94 L.Ed.2d 792 (1987).

been appealed. Remaining claims 1, 3, 7, 8, 14, 15, 19, and 25–27 were rejected under 35 U.S.C. § 112, first paragraph, on the grounds that the disclosure would not enable a person skilled in the art to make and use the invention without undue experimentation. The rejection is directed solely to whether the specification enables one skilled in the art to make the monoclonal antibodies that are needed to practice the invention. The position of the PTO is that data presented by Wands show that the production of high-affinity IgM anti-HBsAg antibodies is unpredictable and unreliable, so that it would require undue experimentation for one skilled in the art to make the antibodies.

III. *Analysis*

A. *Enablement by Deposit of Microorganisms and Cell Lines.*

[1] The first paragraph of 35 U.S.C. § 112 requires that the specification of a patent must enable a person skilled in the art to make and use the claimed invention. "Patents * * * are written to enable those skilled in the art to practice the invention." [3] A patent need not disclose what is well known in the art.[4] Although we review underlying facts found by the board under a "clearly erroneous" standard,[5] we review enablement as a question of law.[6]

[2] Where an invention depends on the use of living materials such as microorganisms or cultured cells, it may be impossible to enable the public to make the invention (i.e., to obtain these living materials) solely by means of a written disclosure. One means that has been developed for complying with the enablement requirement is to deposit the living materials in cell depositories which will distribute samples to the public who wish to practice the invention after the patent issues.[7] Administrative guidelines and judicial decisions have clarified the conditions under which a deposit of organisms can satisfy the requirements of section 112.[8] A deposit has been held necessary for enablement where the starting materials (i.e., the living cells used to practice the invention, or cells from which the required cells can be produced) are not readily available to the public.[9] Even when starting materials are available, a deposit has been necessary where it would require undue experimentation to make the cells of the invention from the starting materials.[10]

In addition to satisfying the enablement requirement, deposit of organisms also can be used to establish the filing date of the application as the prima facie date of inven-

3. *W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1556, 220 USPQ 303, 315 (Fed.Cir. 1983), *cert. denied*, 469 U.S. 851, 105 S.Ct. 172, 83 L.Ed.2d 107 (1984).

4. *Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 1463, 221 USPQ 481, 489 (Fed.Cir.1984).

5. *Coleman v. Dines*, 754 F.2d 353, 356, 224 USPQ 857, 859 (Fed.Cir.1985).

6. *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 1268, 229 USPQ 805, 810 (Fed.Cir. 1986), *cert. denied*, 479 U.S. 1030, 107 S.Ct. 875, 93 L.Ed.2d 829 (1987); *Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 960 n. 6, 220 USPQ 592, 599 n. 6 (Fed.Cir.1983), *cert. denied*, 469 U.S. 835, 105 S.Ct. 127, 83 L.Ed.2d 69 (1984).

7. *In re Argoudelis*, 434 F.2d 1390, 1392–93, 168 USPQ 99, 101–02 (CCPA 1970).

8. *In re Lundak*, 773 F.2d 1216, 227 USPQ 90 (Fed.Cir.1985); *Feldman v. Aunstrup*, 517 F.2d 1351, 186 USPQ 108 (CCPA 1975), *cert. denied*, 424 U.S. 912, 96 S.Ct. 1109, 47 L.Ed.2d 316 (1976); Manual of Patent Examining Procedure (MPEP) 608.01(p)(C) (5th ed. 1983, rev. 1987). *See generally* Hampar, *Patenting of Recombinant DNA Technology: The Deposit Requirement*, 67 J.Pat. Trademark Off. Soc'y 569 (1985).

9. *In re Jackson*, 217 USPQ 804, 807–08 (Bd.App. 1982) (strains of a newly discovered species of bacteria isolated from nature); *Feldman*, 517 F.2d 1351, 186 USPQ 108 (uncommon fungus isolated from nature); *In re Argoudelis*, 434 F.2d at 1392, 168 USPQ at 102 (novel strain of antibiotic-producing microorganism isolated from nature); *In re Kropp*, 143 USPQ 148, 152 (Bd.App. 1959) (newly discovered microorganism isolated from soil).

10. *In re Forman*, 230 USPQ 546, 547 (Bd.Pat. App. & Int.1986) (genetically engineered bacteria where the specification provided insufficient information about the amount of time and effort required); *In re Lundak*, 773 F.2d 1216, 227 USPQ 90 (unique cell line produced from another cell line by mutagenesis).

tion,[11] and to satisfy the requirement under 35 U.S.C. § 114 that the PTO be guaranteed access to the invention during pendency of the application.[12] Although a deposit may serve these purposes, we recognized, in *In re Lundak*,[13] that these purposes, nevertheless, may be met in ways other than by making a deposit.

A deposit also may satisfy the best mode requirement of section 112, first paragraph, and it is for this reason that the 1F8 hybridoma was deposited in connection with the '145 patent and the current application. Wands does not challenge the statements by the examiner to the effect that, although the deposited 1F8 line enables the public to perform immunoassays with antibodies produced by that single hybridoma, the deposit does not enable the generic claims that are on appeal. The examiner rejected the claims on the grounds that the written disclosure was not enabling and that the deposit was inadequate. Since we hold that the written disclosure fully enables the claimed invention, we need not reach the question of the adequacy of deposits.

B. *Undue Experimentation.*

[3–5] Although inventions involving microorganisms or other living cells often can be enabled by a deposit,[14] a deposit is not always necessary to satisfy the enablement requirement.[15] No deposit is necessary if the biological organisms can be obtained from readily available sources or derived from readily available starting materials through routine screening that does not require undue experimentation.[16] Whether the specification in an application involving living cells (here, hybridomas) is enabled without a deposit must be decided on the facts of the particular case.[17]

[6] Appellants contend that their written specification fully enables the practice of their claimed invention because the monoclonal antibodies needed to perform the immunoassays can be made from readily available starting materials using methods that are well known in the monoclonal antibody art. Wands states that application of these methods to make high-affinity IgM anti-HBsAg antibodies requires only routine screening, and that does not amount to undue experimentation. There is no challenge to their contention that the starting materials (i.e., mice, HBsAg antigen, and myeloma cells) are available to the public. The PTO concedes that the methods used to prepare hybridomas and to screen them for high-affinity IgM antibodies against HBsAg were either well known in the monoclonal antibody art or adequately disclosed in the '145 patent and in the current application. This is consistent with this court's recognition with respect to another patent application that methods for obtaining and screening monoclonal antibodies were well known in 1980.[18] The sole issue is whether, in this particular case, it would require undue experimentation to produce high-affinity IgM monoclonal antibodies.

[7] Enablement is not precluded by the necessity for some experimentation such as

11. *In re Lundak*, 773 F.2d at 1222, 227 USPQ at 95–96; *In re Feldman*, 517 F.2d at 1355, 186 USPQ at 113; *In re Argoudelis*, 434 F.2d at 1394–96, 168 USPQ at 103–04 (Baldwin, J. concurring).

12. *In re Lundak*, 773 F.2d at 1222, 227 USPQ at 95–96; *In re Feldman*, 517 F.2d at 1354, 186 USPQ at 112.

13. *In re Lundak*, 773 F.2d at 1222, 227 USPQ at 95–96.

14. *In re Argoudelis*, 434 F.2d at 1393, 168 USPQ at 102.

15. *Tabuchi v. Nubel*, 559 F.2d 1183, 194 USPQ 521 (CCPA 1977).

16. *Id.* at 1186–87, 194 USPQ at 525; *Merck & Co. v. Chase Chem. Co.*, 273 F.Supp. 68, 77, 155 USPQ 139, 146 (D.N.J.1967); *Guaranty Trust Co. v. Union Solvents Corp.*, 54 F.2d 400, 403–06, 12 USPQ 47, 50–53 (D.Del.1931), *aff'd*, 61 F.2d 1041, 15 USPQ 237 (3d Cir.1932), *cert. denied*, 288 U.S. 614, 53 S.Ct. 405, 77 L.Ed. 987 (1933); MPEP 608.01(p)(C) ("No problem exists when the microorganisms used are known and readily available to the public.").

17. *In re Jackson*, 217 USPQ at 807; *see In re Metcalfe*, 410 F.2d 1378, 1382, 161 USPQ 789, 792 (CCPA 1969).

18. *Hybritech*, 802 F.2d at 1384, 231 USPQ at 94.

routine screening.[19] However, experimentation needed to practice the invention must not be undue experimentation.[20] "The key word is 'undue,' not 'experimentation.'" [21]

The determination of what constitutes undue experimentation in a given case requires the application of a standard of reasonableness, having due regard for the nature of the invention and the state of the art. *Ansul Co. v. Uniroyal, Inc.* [448 F.2d 872, 878–79; 169 USPQ 759, 762–63 (2d Cir.1971), *cert. denied*, 404 U.S. 1018, 92 S.Ct. 680, 30 L.Ed.2d 666 (1972)]. The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed * * *.[22]

[8] The term "undue experimentation" does not appear in the statute, but it is well established that enablement requires that the specification teach those in the art to make and use the invention without undue experimentation.[23] Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations. The board concluded that undue experimentation would be needed to practice the invention on the basis of experimental data presented by Wands. These data are not in dispute. However, Wands and the board disagree strongly on the conclusion that should be drawn from that data.

[9] Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in *In re Forman*.[24] They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.[25]

In order to understand whether the rejection was proper, it is necessary to discuss further the methods for making specific monoclonal antibodies. The first step for making monoclonal antibodies is to immunize an animal. The '145 patent provides a detailed description of procedures for immunizing a specific strain of mice against HBsAg. Next the spleen, an organ rich in lymphocytes, is removed and the lymphocytes are separated from the other spleen cells. The lymphocytes are mixed with myeloma cells, and the mixture is treated to cause a few of the cells to fuse with each other. Hybridoma cells that secrete the desired antibodies then must be isolated from the enormous number of other cells in the mixture. This is done through a series of screening procedures.

The first step is to separate the hybridoma cells from unfused lymphocytes and myeloma cells. The cells are cultured in a medium in which all the lymphocytes and myeloma cells die, and only the hybridoma cells survive. The next step is to isolate and clone hybridomas that make antibodies

19. *Id.; Atlas Powder Co. v. E.I. DuPont De Nemours & Co.*, 750 F.2d 1569, 1576, 224 USPQ 409, 413 (Fed.Cir.1984); *In re Angstadt*, 537 F.2d at 502–504, 190 USPQ at 218; *In re Geerdes*, 491 F.2d 1260, 1265, 180 USPQ 789, 793 (CCPA 1974); *Mineral Separation, Ltd. v. Hyde*, 242 U.S. 261, 270–71, 37 S.Ct. 82, 86, 61 L.Ed. 286 (1916).

20. *Hybritech*, 802 F.2d at 1384, 231 USPQ at 94; *W.L. Gore*, 721 F.2d at 1557, 220 USPQ at 316; *In re Colianni*, 561 F.2d 220, 224, 195 USPQ 150, 153 (CCPA 1977) (Miller, J., concurring).

21. *In re Angstadt*, 537 F.2d at 504, 190 USPQ at 219.

22. *In re Jackson*, 217 USPQ at 807.

23. *See Hybritech*, 802 F.2d at 1384, 231 USPQ at 94; *Atlas Powder*, 750 F.2d at 1576, 224 USPQ at 413.

24. *In re Forman*, 230 USPQ at 547.

25. *Id.; see In re Colianni*, 561 F.2d at 224, 195 USPQ at 153 (Miller, J., concurring); *In re Rainer*, 347 F.2d 574, 577, 146 USPQ 218, 221 (CCPA 1965).

that bind to the antigen of interest. Single hybridoma cells are placed in separate chambers and are allowed to grow and divide. After there are enough cells in the clone to produce sufficient quantities of antibody to analyze, the antibody is assayed to determine whether it binds to the antigen. Generally, antibodies from many clones do not bind the antigen, and these clones are discarded. However, by screening enough clones (often hundreds at a time), hybridomas may be found that secrete antibodies against the antigen of interest.

Wands used a commercially available radioimmunoassay kit to screen clones for cells that produce antibodies directed against HBsAg. In this assay the amount of radioactivity bound gives some indication of the strength of the antibody-antigen binding, but does not yield a numerical affinity constant, which must be measured using the more laborious Scatchard analysis. In order to determine which anti-HBsAg antibodies satisfy all of the limitations of appellants' claims, the antibodies require further screening to select those which have an IgM isotype and have a binding affinity constant of at least 10^9 M^{-1}.[26] The PTO does not question that the screening techniques used by Wands were well known in the monoclonal antibody art.

During prosecution Wands submitted a declaration under 37 C.F.R. § 1.132 providing information about all of the hybridomas that appellants had produced before filing the patent application. The first four fusions were unsuccessful and produced no hybridomas. The next six fusion experiments all produced hybridomas that made antibodies specific for HBsAg. Antibodies that bound at least 10,000 cpm in the commercial radioimmunoassay were classified as "high binders." Using this criterion, 143 high-binding hybridomas were obtained. In the declaration, Wands stated that[27]

> It is generally accepted in the art that, among those antibodies which are binders with 50,000 cpm or higher, there is a very high likelihood that high affinity (Ka [greater than] 10^9 M^{-1}) antibodies will be found. However, high affinity antibodies can also be found among high binders of between 10,000 and 50,000, as is clearly demonstrated in the Table.

The PTO has not challenged this statement.

The declaration stated that a few of the high-binding monoclonal antibodies from two fusions were chosen for further screening. The remainder of the antibodies and the hybridomas that produced them were saved by freezing. Only nine antibodies were subjected to further analysis. Four (three from one fusion and one from another fusion) fell within the claims, that is, were IgM antibodies and had a binding affinity constant of at least 10^9 M^{-1}. Of the remaining five antibodies, three were found to be IgG, while the other two were IgM for which the affinity constants were not measured (although both showed binding well above 50,000 cpm).

Apparently none of the frozen cell lines received any further analysis. The declaration explains that after useful high-affinity IgM monoclonal antibodies to HBsAg had been found, it was considered unnecessary to return to the stored antibodies to screen for more IgMs. Wands says that the existence of the stored hybridomas was disclosed to the PTO to comply with the requirement under 37 C.F.R. § 1.56 that applicants fully disclose all of their relevant

26. The examiner, the board, and Wands all point out that, technically, the strength of antibody-HBsAg binding is measured as *avidity*, which takes into account multiple determinants on the HBsAg molecule, rather than affinity. Nevertheless, despite this correction, all parties then continued to use the term "affinity." We will use the terminology of the parties. Following the usage of the parties, we will also use the term "high-affinity" as essentially synonymous with "having a binding affinity constant of at least 10^9 M^{-1}."

27. A table in the declaration presented the binding data for antibodies from every cell line. Values ranged from 13,867 to 125,204 cpm, and a substantial proportion of the antibodies showed binding greater than 50,000 cpm. In confirmation of Dr. Wand's statement, two antibodies with binding less than 25,000 cpm were found to have affinity constants greater than 10^9 M^{-1}.

data, and not just favorable results.[28] How these stored hybridomas are viewed is central to the positions of the parties.

The position of the board emphasizes the fact that since the stored cell lines were not completely tested, there is no proof that any of them are IgM antibodies with a binding affinity constant of at least 10^9 M^{-1}. Thus, only 4 out of 143 hybridomas, or 2.8 percent, were *proved* to fall within the claims. Furthermore, antibodies that were proved to be high-affinity IgM came from only 2 of 10 fusion experiments. These statistics are viewed by the board as evidence that appellants' methods were not predictable or reproducible. The board concludes that Wands' low rate of demonstrated success shows that a person skilled in the art would have to engage in undue experimentation in order to make antibodies that fall within the claims.

Wands views the data quite differently. Only nine hybridomas were actually analyzed beyond the initial screening for HBsAg binding. Of these, four produced antibodies that fell within the claims, a respectable 44 percent rate of success. (Furthermore, since the two additional IgM antibodies for which the affinity constants were never measured showed binding in excess of 50,000 cpm, it is likely that these also fall within the claims.) Wands argues that the remaining 134 unanalyzed, stored cell lines should not be written off as failures. Instead, if anything, they represent partial success. Each of the stored hybridomas had been shown to produce a high-binding antibody specific for HBsAg. Many of these antibodies showed binding above 50,000 cpm and are thus highly likely to have a binding affinity constant of at least 10^9 M^{-1}. Extrapolating from the nine hybridomas that were screened for isotype (and from what is well known in the monoclonal antibody art about isotype frequency), it is reasonable to assume that the stored cells include some that produce IgM. Thus, if the 134 incompletely analyzed cell lines are considered at all, they provide some support (albeit without rigorous proof) to the view that hybridomas falling within the claims are not so rare that undue experimentation would be needed to make them.

The first four fusion attempts were failures, while high-binding antibodies were produced in the next six fusions. Appellants contend that the initial failures occurred because they had not yet learned to fuse cells successfully. Once they became skilled in the art, they invariably obtained numerous hybridomas that made high-binding antibodies against HBsAg and, in each fusion where they determined isotype and binding affinity they obtained hybridomas that fell within the claims.

Wands also submitted a second declaration under 37 C.F.R. § 1.132 stating that after the patent application was submitted they performed an eleventh fusion experiment and obtained another hybridoma that made a high-affinity IgM anti-HBsAg antibody. No information was provided about the number of clones screened in that experiment. The board determined that, because there was no indication as to the number of hybridomas screened, this declaration had very little value. While we agree that it would have been preferable if Wands had included this information, the declaration does show that when appellants repeated their procedures they again obtained a hybridoma that produced an antibody that fit all of the limitations of their claims.

We conclude that the board's interpretation of the data is erroneous. It is strained and unduly harsh to classify the stored cell lines (each of which was proved to make high-binding antibodies against HBsAg) as failures demonstrating that Wands' methods are unpredictable or unreliable.[29] At worst, they prove nothing at all about the probability of success, and merely show

28. *See Rohm & Haas Co. v. Crystal Chem. Co.*, 722 F.2d 1556, 220 USPQ 289 (Fed.Cir.1983).

29. Even if we were to accept the PTO's 2.8% success rate, we would not be required to reach a conclusion of undue experimentation. Such a determination must be made in view of the circumstances of each case and cannot be made solely by reference to a particular numerical cutoff.

that appellants were prudent in not discarding cells that might someday prove useful. At best, they show that high-binding antibodies, the starting materials for IgM screening and Scatchard analysis, can be produced in large numbers. The PTO's position leads to the absurd conclusion that the more hybridomas an applicant makes and saves without testing, the less predictable the applicant's results become. Furthermore, Wands' explanation that the first four attempts at cell fusion failed only because they had not yet learned to perform fusions properly is reasonable in view of the fact that the next six fusions were all successful. The record indicates that cell fusion is a technique that is well known to those of ordinary skill in the monoclonal antibody art, and there has been no claim that the fusion step should be more difficult or unreliable where the antigen is HBsAg than it would be for other antigens.

When Wands' data is interpreted in a reasonable manner, analysis considering the factors enumerated in *In re Forman* leads to the conclusion that undue experimentation would not be required to practice the invention. Wands' disclosure provides considerable direction and guidance on how to practice their invention and presents working examples. There was a high level of skill in the art at the time when the application was filed, and all of the methods needed to practice the invention were well known.

The nature of monoclonal antibody technology is that it involves screening hybridomas to determine which ones secrete antibody with desired characteristics. Practitioners of this art are prepared to screen negative hybridomas in order to find one that makes the desired antibody. No evidence was presented by either party on how many hybridomas would be viewed by those in the art as requiring undue experimentation to screen. However, it seems unlikely that undue experimentation would be defined in terms of the number of hybridomas that were never screened. Furthermore, in the monoclonal antibody art it appears that an "experiment" is not simply the screening of a single hybridoma, but is rather the entire attempt to make a monoclonal antibody against a particular antigen. This process entails immunizing animals, fusing lymphocytes from the immunized animals with myeloma cells to make hybridomas, cloning the hybridomas, and screening the antibodies produced by the hybridomas for the desired characteristics. Wands carried out this entire procedure three times, and was successful each time in making at least one antibody that satisfied all of the claim limitations. Reasonably interpreted, Wands' record indicates that, in the production of high-affinity IgM antibodies against HBsAG, the amount of effort needed to obtain such antibodies is not excessive. Wands' evidence thus effectively rebuts the examiner's challenge to the enablement of their disclosure.[30]

IV. *Conclusion*

Considering all of the factors, we conclude that it would not require undue experimentation to obtain antibodies needed to practice the claimed invention. Accordingly, the rejection of Wands' claims for lack of enablement under 35 U.S.C. § 112, first paragraph, is reversed.

REVERSED

PAULINE NEWMAN, Circuit Judge, concurring in part, dissenting in part.

A

I concur in the court's holding that additional samples of hybridoma cell lines that produce these high-affinity IgM monoclonal antibodies need not be deposited. This invention, as described by Wands, is not a selection of a few rare cells from many possible cells. To the contrary, Wands states that all monoclonally produced IgM antibodies to hepatitis B surface antigen have the desired high avidity and other favorable properties, and that all are readily preparable by now-standard techniques.

Wands states that his United States Patent No. 4,271,145 describes fully operable techniques, and is distinguished from his

30. *In re Strahilevitz*, 668 F.2d 1229, 1232, 212 USPQ 561, 563 (CCPA 1982).

first four failed experiments that are referred to in the Rule 132 affidavit. Wands argues that these biotechnological mechanisms are relatively well understood and that the preparations can be routinely duplicated by those of skill in this art, as in *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1380, 231 USPQ 81, 94 (Fed.Cir.1986), *cert. denied*, — U.S. —, 107 S.Ct. 1606, 94 L.Ed.2d 792 (1987). I agree that it is not necessary that there be a deposit of multiple exemplars of a cell system that is readily reproduced by known, specifically identified techniques.

B

I would affirm the board's holding that Wands has not complied with 35 U.S.C. § 112, first paragraph, in that he has not provided data sufficient to support the breadth of his generic claims. Wands' claims on appeal include the following:

> 19. Monoclonal high affinity IgM antibodies immunoreactive with HBsAg determinants, wherein said antibodies are coupled to an insoluble solid phase, and wherein the binding affinity constant of said antibodies for said HBsAg determinants is at least 10^9 M^{-1}.
>
> 26. Monoclonal high affinity IgM antibodies immunoreactive with HBsAg determinants wherein said antibodies are detectably labelled.

Wands states that he obtained 143 "high binding monoclonal antibodies of the right specificity" in the successful fusions; although he does not state how they were determined to be high binding or of the right specificity, for Wands also states that only nine of these 143 were tested.

Of these nine, four (three from one fusion and one from another fusion) were found to have the claimed high affinity and to be of the IgM isotype. Wands states that the other five were either of a different isotype or their affinities were not determined. (This latter statement also appears to contradict his statement that all 143 were "high binding".)

Wands argues that a "success rate of four out of nine", or 44.4%, is sufficient to support claims to the entire class. The Commissioner deems the success rate to be four out of 143, or 2.8%; to which Wands responds with statistical analysis as to how unlikely it is that Wands selected the only four out of 143 that worked. Wands did not, however, prove the right point. The question is whether Wands, by testing nine out of 143 (the Commissioner points out that the randomness of the sample was not established), and finding that four out of the nine had the desired properties, has provided sufficient experimental support for the breadth of the requested claims, in the context that "experiments in genetic engineering produce, at best, unpredictable results", quoting from *Ex parte Forman*, 230 USPQ 546, 547 (Bd.Pat.App. and Int. 1986).

The premise of the patent system is that an inventor, having taught the world something it didn't know, is encouraged to make the product available for public and commercial benefit, by governmental grant of the right to exclude others from practice of that which the inventor has disclosed. The boundary defining the excludable subject matter must be carefully set: it must protect the inventor, so that commercial development is encouraged; but the claims must be commensurate with the inventor's contribution. Thus the specification and claims must meet the requirements of 35 U.S.C. § 112. *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 23–24 (CCPA 1970).

As the science of biotechnology matures the need for special accommodation, such as the deposit of cell lines or microorganisms, may diminish; but there remains the body of law and practice on the need for sufficient disclosure, including experimental data when appropriate, that reasonably support the scope of the requested claims. That law relates to the sufficiency of the description of the claimed invention, and if not satisfied by deposit, must independently meet the requirements of Section 112.

Wands is not claiming a particular, specified IgM antibody. He is claiming all such monoclonal antibodies in assay for hepatitis B surface antigen, based on his teaching that such antibodies have uniformly reproducible high avidity, free of the known

disadvantages of IgM antibodies such as tendency to precipitate or aggregate. It is incumbent upon Wands to provide reasonable support for the proposed breadth of his claims. I agree with the Commissioner that four exemplars shown to have the desired properties, out of the 143, do not provide adequate support.

Wands argues that the law should not be "harsher" where routine experiments take a long time. However, what Wands is requesting is that the law be less harsh. As illustrated in extensive precedent on the question of how much experimentation is "undue", each case must be determined on its own facts. *See, e.g., W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1557, 220 USPQ 303, 316 (Fed.Cir.1983), *cert. denied*, 469 U.S. 851, 105 S.Ct. 172, 83 L.Ed.2d 107 (1984); *In re Angstadt*, 537 F.2d 498, 504, 190 USPQ 214, 218 (CCPA 1976); *In re Cook*, 439 F.2d 730, 734–35, 169 USPQ 298, 302–03 (CCPA 1971).

The various criteria to be considered in determining whether undue experimentation is required are discussed in, for example, *Fields v. Conover*, 443 F.2d 1386, 170 USPQ 276 (CCPA 1971); *In re Rainer*, 347 F.2d 574, 146 USPQ 218 (CCPA 1965); *Ex parte Forman*, 230 USPQ at 547. Wands must provide sufficient data or authority to show that his results are reasonably predictable within the scope of the claimed generic invention, based on experiment and/or scientific theory. In my view he has not met this burden.

BANTAM TRAVELWARE, DIV. OF PETER'S BAG CORP.,
Plaintiff–Appellant,

v.

The UNITED STATES,
Defendant–Appellee.

No. 88–1217.

United States Court of Appeals, Federal Circuit.

Oct. 4, 1988.

Appealed from U.S. Court of International Trade; Tsoucalas, Judge.

Judith M. Barzilay, Siegel, Mandell & Davidson, P.C., of New York City, argued, for plaintiff-appellant. With her on the brief, was Brian S. Goldstein, New York City.

James A. Curley, Commercial Litigation Branch, Dept. of Justice, New York City, argued, for defendant-appellee. With him on the brief, were John R. Bolton, Asst. Atty. Gen., David M. Cohen, Director, Washington, D.C., and Joseph I. Liebman, Atty. in Charge, Intern. Trade Field Office, New York City.

Before MAYER and MICHEL, Circuit Judges, and NICHOLS, Senior Circuit Judge.

PER CURIAM.

The judgment of the United States Court of International Trade, 679 F.Supp. 8 (1987), is affirmed on the basis of the court's opinion, which we adopt.

AFFIRMED.

nell "assumed the risk of unavailable milling time", and that Connell's contract obligations were not conditioned thereon.

[3] Both the board, and the government in its brief, offer theories as to how Connell might have managed, at whatever cost, to obtain milled rice for timely delivery. These theories, in view of the USDA regulations, are relevant only to the question of whether Connell's failure to perform was "beyond [its] control and without [its] fault or negligence". If the government created the situation that caused or contributed to Connell's late delivery, it can not be held as a matter of law that Connell was required to exceed reasonable efforts in order to compensate for this unwarranted government action.

The government cites *Jennie-O Foods, Inc., v. United States*, 580 F.2d 400, 409–10 (Ct.Cl.1978), which held that "unanticipated economic hardship" did not excuse failure to perform where the contractor had not shown that "the product (healthy turkeys) was unavailable within the boundaries of a reasonable area." There was no issue in *Jennie-O* of governmental contribution to the failure to perform; nor was a theory of strict liability applied. The issues there raised, as here, are fact-dependent, and in *Jennie-O* were fully developed at trial.

[4] Connell must be enabled to develop the facts pertinent to its defense that the government, acting in its sovereign or contractual capacities, contributed to the delay; the extent of that contribution; and whether Connell was at fault or negligent; for these facts are material to the issues of liability, and the extent thereof. The determination must be made as to whether exculpation has been shown under the circumstances. Public policy and the national interest, as well as the principles of contract law, so require. As the Court explained in *United States v. Brooks-Calloway Co.*, 318 U.S. 120, 122, 63 S.Ct. 474, 476, 87 L.Ed. 653 (1943), the purpose of the standard proviso in government contracts that authorizes such relief is:

> Thus contractors know they are not to be penalized for unexpected impediments to prompt performance, and, since their bids can be based on foreseeable and probable, rather than possible hindrances, the Government secures the benefit of lower bids and an enlarged selection of bidders.

Although the government argues that Connell "failed to meet its burden" on summary judgment, the denial of discovery related to this defense contributed to this failure.

REVERSED AND REMANDED.

In re David H. FINE

No. 87-1319.

United States Court of Appeals, Federal Circuit.

Jan. 26, 1988.

The Board of Patent Appeals and Interferences of the United States Patent and Trademark Office affirmed rejection of claims of application for patent for system for detecting and measuring minute quantities of nitrogen compounds, and applicant appealed. The Court of Appeals, Mayer, Circuit Judge, held that: (1) it would not have been obvious to substitute nitric oxide detector for sulfur dioxide detector in prior system, and (2) sulfur detection system did not teach use of claimed temperature range.

Reversed.

Edward S. Smith, Circuit Judge, dissented and filed opinion.

1. Patents ⇐16.33

System for detecting and measuring minute quantities of nitrogen compounds was not obvious in light of prior art for separating, identifying, and monitoring sulfur compounds or method for measuring chemiluminescence of reaction between ni-

tric oxide and ozone which required continuous flowing of gaseous mixture into reaction chamber; method for measuring sulfur deliberately sought to avoid nitrogen compounds, and claimed invention retained each nitrogen compound constituent of gaseous sample in chromatograph for individual time period. 35 U.S.C.A. § 103.

2. Patents ⇐114.19, 114.21

Patent and Trademark Office has burden to establish prima facie case of obviousness, which it may satisfy only by showing some objective teaching in prior art, or that knowledge generally available to one of ordinary skill and art would lead that individual to combined relevant teachings of references. 35 U.S.C.A. § 103.

3. Patents ⇐26(1)

Whether particular combination might be "obvious to try" is not legitimate test of patentability. 35 U.S.C.A. § 103.

4. Patents ⇐16.5

Patent which described preferred temperature range for separating, identifying and quantitatively monitoring sulfur compounds could be distinguished from claimed method for detecting and measuring minute quantities of nitrogen compounds which limited temperature to prevent nitrogen from other sources, where purpose of temperature limitation in prior art was to avoid formation of unwanted sulfides.

Morris Relson, Darby & Darby, P.C., New York City, for appellant. With him on the brief was Beverly B. Goodwin.

Lee E. Barrett, Associate Sol., Office of the Solicitor, Arlington, Va., for appellee. With him on the brief were Joseph F. Nakamura, Sol. and Fred E. McKelvey, Deputy Sol.

Before FRIEDMAN, SMITH and MAYER, Circuit Judges.

OPINION

MAYER, Circuit Judge.

David H. Fine appeals from a decision of the Board of Patent Appeals and Interferences of the United States Patent and Trademark Office (Board) affirming the rejection of certain claims of his application, Serial No. 512,374, and concluding that his invention would have been obvious to one of ordinary skill in the art and was therefore unpatentable under 35 U.S.C. § 103. We reverse.

BACKGROUND

A. The Invention.

The invention claimed is a system for detecting and measuring minute quantities of nitrogen compounds. According to Fine, the system has the ability to detect the presence of nitrogen compounds in quantities as minute as one part in one billion, and is an effective means to detect drugs and explosives, which emanate nitrogen compound vapors even when they are concealed in luggage and closed containers.

The claimed invention has three major components: (1) a gas chromatograph which separates a gaseous sample into its constituent parts; (2) a converter which converts the nitrogen compound effluent output of the chromatograph into nitric oxide in a hot, oxygen-rich environment; and (3) a detector for measuring the level of nitric oxide. The claimed invention's sensitivity is achieved by combining nitric oxide with ozone to produce nitrogen dioxide which concurrently causes a detectable luminescence. The luminescence, which is measured by a visual detector, shows the level of nitric oxide which in turn is a measure of nitrogen compounds found in the sample.

The appealed claims were rejected by the Patent and Trademark Office (PTO) under 35 U.S.C. § 103. Claims 60, 63, 77 and 80 were rejected as unpatentable over Eads, Patent No. 3,650,696 (Eads) in view of Warnick, et al., Patent No. 3,746,513 (Warnick). Claims 62, 68, 69, 79, 85 and 86 were rejected as unpatentable over Eads and Warnick in view of Glass, et al., Patent No. 3,207,585 (Glass).

B. The Prior Art.

1. *Eads Patent.*

Eads discloses a method for separating, identifying and quantitatively monitoring

sulfur compounds. The Eads system is used primarily in "air pollution control work in the scientific characterization of odors from sulfur compounds."

The problem addressed by Eads is the tendency of sulfur compounds "to adhere to or react with the surface materials of the sampling and analytical equipment, and/or react with the liquid or gaseous materials in the equipment." Because of this, the accuracy of measurement is impaired. To solve the problem, the Eads system collects an air sample containing sulfur compounds in a sulfur-free methanol solution. The liquid is inserted into a gas chromatograph which separates the various sulfur compounds. The compounds are next sent through a pyrolysis furnace where they are oxidized to form sulfur dioxide. Finally, the sulfur dioxide passes through a measuring device called a microcoulometer which uses titration cells to calculate the concentration of sulfur compounds in the sample.

2. *Warnick Patent.*

Warnick is directed to a means for detecting the quantity of pollutants in the atmosphere. By measuring the chemiluminescence of the reaction between nitric oxide and ozone, the Warnick device can detect the concentration of nitric oxide in a sample gaseous mixture.

Warnick calls for "continuously flowing" a sample gaseous mixture and a reactant containing ozone into a reaction chamber. The chemiluminescence from the resulting reaction is transmitted through a light-transmitting element to produce continuous readouts of the total amount of nitric oxide present in the sample.

3. *Glass Patent.*

The invention disclosed in Glass is a device for "completely burning a measured amount of a substance and analyzing the combustion products." A fixed amount of a liquid petroleum sample and oxygen are supplied to a flame. The flame is then spark-ignited, causing the sample to burn. The resulting combustion products are then collected and measured, and from this measurement the hydrogen concentration in the sample is computed.

C. The Rejection.

The Examiner rejected claims 60, 63, 77 and 80 because "substitution of the [nitric oxide] detector of Warnick for the sulfur detector of Eads would be an obvious consideration if interested in nitrogen compounds, and would yield the claimed invention." He further asserted that "Eads teaches the [claimed] combination of chromatograph, combustion, and detection, in that order. . . . Substitution of detectors to measure any component of interest is well within the skill of the art." In rejecting claims 62, 68, 69, 79, 85 and 86, the Examiner said, "Glass et al. teach a flame conversion means followed by a detector, and substitution of the flame conversion means of Glass et al. for the furnace of Eads would be an obvious equivalent and would yield the claimed invention." The Board affirmed the Examiner's rejection.

DISCUSSION

A. Standard of Review.

Obviousness under 35 U.S.C. § 103 is " 'a legal conclusion based on factual evidence.' " *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1535, 218 USPQ 871, 876 (Fed.Cir.1983) (quoting *Stevenson v. Int'l Trade Comm'n*, 612 F.2d 546, 549, 204 USPQ 276, 279 (CCPA 1979)). Therefore, an obviousness determination is not reviewed under the clearly erroneous standard applicable to fact findings, *Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 956, 220 USPQ 592, 596 (Fed.Cir.1983); it is "reviewed for correctness or error as a matter of law." *In re De Blauwe*, 736 F.2d 699, 703, 222 USPQ 191, 195 (Fed.Cir.1984).

To reach a proper conclusion under § 103, the decisionmaker must step backward in time and into the shoes worn by [a person having ordinary skill in the art] when the invention was unknown and just before it was made. In light of *all* the evidence, the decisionmaker must then determine whether . . . the claimed invention as a whole would have been

> obvious at *that* time to *that* person. 35 U.S.C. § 103. The answer to that question partakes more of the nature of law than of fact, for it is an ultimate conclusion based on a foundation formed of all the probative facts.

Panduit Corp. v. Dennison Mfg. Co., 810 F.2d 1561, 1566, 1 USPQ2d 1593, 1595–96 (Fed.Cir.1987).

B. Prima Facie Obviousness.

Fine says the PTO has not established a *prima facie* case of obviousness. He contends the references applied by the Board and Examiner were improperly combined, using hindsight reconstruction, without evidence to support the combination and in the face of contrary teachings in the prior art. He argues that the appealed claims were rejected because the PTO thought it would have been "obvious to try" the claimed invention, an unacceptable basis for rejection.

[1, 2] We agree. The PTO has the burden under section 103 to establish a *prima facie* case of obviousness. *See In re Piasecki*, 745 F.2d 1468, 1471–72, 223 USPQ 785, 787–88 (Fed.Cir.1984). It can satisfy this burden only by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the references. *In re Lalu*, 747 F.2d 703, 705, 223 USPQ 1257, 1258 (Fed.Cir.1984); *see also Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 297 n. 24, 227 USPQ 657, 667 n. 24 (Fed.Cir.1985); *ACS Hosp. Sys., Inc. v. Montefiore Hosp.*, 732 F.2d 1572, 1577, 221 USPQ 929, 933 (Fed. Cir.1984). This it has not done. The Board points to nothing in the cited references, either alone or in combination, suggesting or teaching Fine's invention.

The primary basis for the Board's affirmance of the Examiner's rejection was that it would have been obvious to substitute the Warnick nitric oxide detector for the Eads sulfur dioxide detector in the Eads system. The Board reiterated the Examiner's bald assertion that "substitution of one type of detector for another in the system of Eads would have been within the skill of the art," but neither of them offered any support for or explanation of this conclusion.

Eads is limited to the analysis of sulfur compounds. The particular problem addressed there is the difficulty of obtaining precise measurements of sulfur compounds because of the tendency of sulfur dioxide to adhere to or react with the sampling analytic equipment or the liquid or gaseous materials in the equipment. It solves this problem by suggesting that the gaseous sample containing sulfur compounds be absorbed into sulfur-free methanol and then inserted into a gas chromatograph to separate the sulfur compounds.

There is no suggestion in Eads, which focuses on the unique difficulties inherent in the measurement of sulfur, to use that arrangement to detect nitrogen compounds. In fact, Eads says that the presence of nitrogen is undesirable because the concentration of the titration cell components in the sulfur detector is adversely affected by substantial amounts of nitrogen compounds in the sample. So, instead of suggesting that the system be used to detect nitrogen compounds, Eads deliberately seeks to avoid them; it warns against rather than teaches Fine's invention. *See W.L. Gore & Assoc. v. Garlock, Inc.*, 721 F.2d 1540, 1550, 220 USPQ 303, 311 (Fed.Cir. 1983) (error to find obviousness where references "diverge from and teach away from the invention at hand"). In the face of this, one skilled in the art would not be expected to combine a nitrogen-related detector with the Eads system. Accordingly, there is no suggestion to combine Eads and Warnick.

Likewise, the teachings of Warnick are inconsistent with the claimed invention, to some extent. The Warnick claims are directed to a gas stream from engine exhaust "continuously flowing the gaseous mixtures into the reaction chamber" to obtain "continuous readouts" of the amount of nitric oxide in the sample. In other words, it contemplates measuring the total amount of nitric oxide in a continuously flowing gaseous mixture of unseparated nitrogen constituents. By contrast, in Fine each

nitrogen compound constituent of the gaseous sample is retained in the chromatograph for an individual time period so that each exits in discrete, time-separated pulses.* By this process, each constituent may be both identified by its position in time sequence, and measured. The claimed system, therefore, diverges from Warnick and teaches advantages not appreciated or contemplated by it.

[3] Because neither Warnick nor Eads, alone or in combination, suggests the claimed invention, the Board erred in affirming the Examiner's conclusion that it would have been obvious to substitute the Warnick nitric oxide detector for the Eads sulfur dioxide detector in the Eads system. *ACS Hosp. Sys.*, 732 F.2d at 1575–77, 221 USPQ at 931–33. The Eads and Warnick references disclose, at most, that one skilled in the art might find it obvious to try the claimed invention. But whether a particular combination might be "obvious to try" is not a legitimate test of patentability. *In re Geiger*, 815 F.2d 686, 688, 2 USPQ2d 1276, 1278 (Fed.Cir.1987); *In re Goodwin*, 576 F.2d 375, 377, 198 USPQ 1, 3 (CCPA 1978).

Obviousness is tested by "what the combined teachings of the references would have suggested to those of ordinary skill in the art." *In re Keller*, 642 F.2d 413, 425, 208 USPQ 871, 881 (CCPA 1981). But it "cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination." *ACS Hosp. Sys.*, 732 F.2d at 1577, 221 USPQ at 933. And "teachings of references can be combined *only* if there is some suggestion or incentive to do so." *Id.* Here, the prior art contains none.

Instead, the Examiner relies on hindsight in reaching his obviousness determination. But this court has said, "To imbue one of ordinary skill in the art with knowledge of the invention in suit, when no prior art reference or references of record convey or suggest that knowledge, is to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher." *W.L. Gore*, 721 F.2d at 1553, 220 USPQ at 312–13. It is essential that "the decisionmaker forget what he or she has been taught at trial about the claimed invention and cast the mind back to the time the invention was made . . . to occupy the mind of one skilled in the art who is presented only with the references, and who is normally guided by the then-accepted wisdom in the art." *Id.* One cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention.

C. Advantage Not Appreciated by the Prior Art.

[4] The Board erred not only in improperly combining the Eads and Warnick references but also in failing to appreciate that the appealed claims can be distinguished over that combination. A material limitation of the claimed system is that the conversion to nitric oxide occur in the range of 600°C to 1700°C. The purpose of this limitation is to prevent nitrogen from other sources, such as the air, from being converted to nitric oxide and thereby distorting the measurement of nitric oxide derived from the nitrogen compounds of the sample.

The claimed nitric oxide conversion temperature is not disclosed in Warnick. Although Eads describes a preferred temperature of 675°C to 725°C, the purpose of this range is different from that of Fine. Eads requires the 675°C to 725°C range because it affords a temperature low enough to avoid formation of unwanted sulfur trioxide, yet high enough to avoid formation of unwanted sulfides. Fine's temperature

* The Solicitor argues that the contents of Attachment C of Fine's brief were not before the Board and may not properly be considered here. However, we need not rely on Attachment C. It is merely illustrative of the qualitative separation of nitrogen compounds which occurs in Fine's system. The fact that the various constituents exit at discrete intervals is shown by the specification which was before the Board and which may appropriately be considered on appeal. *See, e.g., Astra–Sjuco, A.B. v. United States Int'l Trade Comm'n*, 629 F.2d 682, 686, 207 USPQ 1, 5 (CCPA 1980) (claims must be construed in light of specification).

range, in contrast, does not seek to avoid the formation of sulfur compounds or even nitrogen compounds. It enables the system to break down the nitrogen compounds of the sample while avoiding the destruction of background nitrogen gas. There is a partial overlap, of course, but this is mere happenstance. Because the purposes of the two temperature ranges are entirely unrelated, Eads does not teach use of the claimed range. *See In re Geiger*, 815 F.2d at 688, 2 USPQ2d at 1278. The Board erred by concluding otherwise.

D. Unexpected Results.

Because we reverse for failure to establish a *prima facie* case of obviousness, we need not reach Fine's contention that the Board failed to accord proper weight to the objective evidence of unexpected superior results. *Id.*

E. The "Flame" Claims.

Claims 62, 68, 69, 79, 85 and 86 relate to the oxygen-rich flame conversion means of the claimed invention. These "flame" claims depend from either apparatus claim 60 or method claim 77. Dependent claims are nonobvious under section 103 if the independent claims from which they depend are nonobvious. *Hartness Int'l, Inc. v. Simplimatic Eng'g Co.*, 819 F.2d 1100, 1108, 2 USPQ2d 1826, 1831 (Fed.Cir.1987); *In re Abele*, 684 F.2d 902, 910, 214 USPQ 682, 689 (CCPA 1982); *see also In re Sernaker*, 702 F.2d 989, 991, 217 USPQ 1, 3 (Fed.Cir.1983). In view of our conclusion that claims 60 and 77 are nonobvious, the dependent "flame" claims are also patentable.

CONCLUSION

The Board's decision affirming the Examiner's rejection of claims 60, 62, 63, 68, 69, 77, 79, 80, 85 and 86 of Fine's application as unpatentable over the prior art under 35 U.S.C. § 103 is

REVERSED.

EDWARD S. SMITH, Circuit Judge, dissenting.

I respectfully dissent. I am of the firm belief that the prior art references, relied upon by the PTO to establish its prima facie case of obviousness, in combination teach and suggest Fine's invention to one skilled in the art. Also, I firmly believe that Fine failed to rebut the PTO's prima facie case. On this basis, I would affirm the board's determination sustaining the examiner's rejection, pursuant to 35 U.S.C. § 103, of Fine's claims on appeal before this court.

PETROCHEM SERVICES, INC., Appellant,

v.

The UNITED STATES, Appellee.

No. 87-1382.

United States Court of Appeals, Federal Circuit.

Decided Jan. 26, 1988.

Government contractor appealed decision of the Armed Services Board of Contract Appeals denying contractor's claim for equitable adjustment of contract to remove oil spilled on naval base. The Court of Appeals, Nichols, Senior Circuit Judge, held that Government's duty to disclose superior knowledge was not legally discharged by Navy supervisor's oral representations, unless contractor's representative heard and understood representations.

Vacated and remanded.

1. United States ⇐70(30)

Disclosure of superior knowledge doctrine applies in situations were contractor undertakes to perform without vital knowledge of fact that affects performance costs

> which obligate the Government to an expenditure of funds....

Similarly, 41 C.F.R. § 1.209 (1983) defines "procurement" as

> the acquisition ... from non-Federal sources, of personal property and nonpersonal services (including construction) by such means as purchasing, renting, leasing (including real property), contracting or bartering, but not by seizure, condemnation, donation, or requisition.

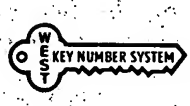
Here there was no "buyer" or "seller" and no obligation on the part of the Government to expend funds. The Claims Court noted that "a cash 'payment' is not the applicable test" of whether a contract comes within the ambit of the CDA. *See Coffey v. United States On Behalf Of The Commodity Credit Corp.*, 626 F.Supp. 1246, 1250 (D.Kan.1986). We are persuaded, however, that the transaction here was closer to being donative in nature than it was to the contracts for procurement of property or services which Congress contemplated including within the scope of the Contract Disputes Act.

We are also not convinced that the transaction was a "barter" contract as found by the Claims Court to support its holding that the CDA was applicable. The September 23, 1983 document merely conditioned acceptance of the LAV virus samples on a promise to refrain from sharing them without permission from Pasteur. Neither that promise nor the Government's implied promise to share the results of future experiments with Pasteur can be considered "specific property susceptible of valuation," as would be required for barter. Black's Law Dictionary 1200 (5th ed. 1979).

Finally, application of complex, burdensome, and inevitably time-consuming procurement regulations to the type of scientific collaboration here involved would "not do justice to the realities of the situation." *Texas State Comm'n For The Blind*, 796 F.2d at 406. The exchange of information and perishable biological products among scientists engaged in collaborative research relating to deadly diseases such as AIDS should not be required to await compliance with procurement regulations such as those requiring a documented determination by a contracting officer that the contractor (here, Pasteur) is "responsible," 41 C.F.R. §§ 1-1.12, 3-1.12 (1983), or a written justification for contracting on a noncompetitive basis, 41 C.F.R. § 3-3.5301 (1983). Moreover, the numerous form clauses required by federal procurement regulations would have no applicability to this type of collaborative research effort. *See, e.g.*, 41 C.F.R. §§ 1-1.318-7, 1-7 (1983). Confirmatory of this is the fact that HHS itself has used a form similar to Pasteur's September 23, 1983 agreement when sending cell lines to other laboratories.

For the foregoing reasons, we are persuaded that the primary function of the pleaded contracts was facilitation of the transfer of research materials among scientists engaged in a collaborative research effort, not procurement of property or services, and that they, therefore, do not fit within the scope of the Contract Disputes Act. Accordingly, we reverse the judgment of the Claims Court and remand the case for consideration of whether there is a valid and enforceable contract, and, if so, whether it has been breached.

REVERSED and REMANDED.



VERDEGAAL BROTHERS, INC., William Verdegaal, George Verdegaal, Appellees,

v.

UNION OIL COMPANY OF CALIFORNIA, Brea Agricultural Services, Inc., Appellants.

Appeal No. 86-1258.

United States Court of Appeals, Federal Circuit.

March 12, 1987.

Action was instituted for alleged patent infringement. The United States Dis-

trict Court for the Eastern District of California, Robert E. Coyle, J., entered judgment on verdict for plaintiff, declaring patent valid and infringed, and defendants appealed. The Court of Appeals, Nies, Circuit Judge, held that patent relating to a process for making urea-sulfuric acid liquid fertilizer by reacting water, urea, a nitrogen-containing chemical, and sulferic acid, a sulfur-containing chemical, in particular proportions was anticipated by prior art reference disclosing processes for making both urea-phosphoric acid and urea-sulferic acid fertilizers and was invalid.

Reversed.

See also, Fed.Cir., 750 F.2d 947.

1. Federal Civil Procedure ⇐2609

A district court presented with a motion for judgment notwithstanding the verdict should consider all of the evidence, in a light most favorable to nonmoving party, drawing all reasonable inferences favorable to that party, without determining credibility of witnesses, and without substituting its choice for that of the jury and deciding between conflicting elements of the evidence, and should grant the motion only when it is convinced upon the record before the jury that reasonable persons could not have reached a verdict for the nonmoving party. 35 U.S.C.A. §§ 102, 103; Fed.Rules Civ.Proc.Rule 50(a, b), 28 U.S.C.A.

2. Federal Civil Procedure ⇐2608

Party moving for judgment notwithstanding the verdict must show that either the jury's factual findings are not supported by substantial evidence, or, if they are, that those findings cannot support the legal conclusions which necessarily were drawn by the jury and forming its verdict. 35 U.S.C.A. §§ 102, 103; Fed.Rules Civ. Proc.Rule 50(a, b), 28 U.S.C.A.

3. Patents ⇐36(2)

Presumption of validity afforded a patent requires that party challenging validity prove facts establishing invalidity by clear and convincing evidence. 35 U.S.C.A. § 282.

4. Patents ⇐72(1)

A claim is anticipated only if each and every element as set forth in claim is found, either expressly or inherently described, in a single prior art reference. 35 U.S.C.A. § 102(e).

5. Patents ⇐66(1.12)

Patent relating to a process for making urea-sulfuric acid liquid fertilizer by reacting water, urea, a nitrogen-containing chemical, and sulferic acid, a sulfur-containing chemical, in particular proportions was anticipated by prior art reference disclosing processes for making both urea-phosphoric acid and urea-sulferic acid fertilizers and was invalid. 35 U.S.C.A. §§ 102(e), 282.

6. Patents ⇐72(1)

It was inappropriate for holder of patented fertilizer process to rely on fact that sulferic acid was added slowly in prior art reference, whereas claimed process allowed for rapid addition, where there was no limitation in subject process with respect to rate at which sulferic acid was added. 35 U.S.C.A. §§ 102(e), 282.

7. Patents ⇐62(1)

Discarding testimony of experts with respect to what prior art reference taught did not eliminate reference itself as evidence or its uncontradicted disclosure that a base of recycled fertilizer in a process could be used to make more of the product and, hence, did not preclude conclusion that claimed process for making liquid fertilizer was invalid as anticipated by prior art. 35 U.S.C.A. §§ 102(e), 282.

8. Patents ⇐72(1)

Failure of prior art reference to explicitly identify heel in process for manufacturing liquid fertilizer as a heat sink did not preclude reference from anticipating claimed process, thus requiring a finding of invalidity, where fact that heel functioned as a heat sink was inherent in prior art reference. 35 U.S.C.A. §§ 102(e), 282.

Andrew J. Belansky, Christie, Parker & Hale, Pasadena, Cal., argued for appel-

lants. With him on the brief was David A. Dillard.

John P. Sutton, Limbach, Limbach & Sutton, San Francisco, Cal., argued for appellees. With him on the brief was Michael E. Dergosits.

Before MARKEY, Chief Judge, and DAVIS and NIES, Circuit Judges.

NIES, Circuit Judge.

Union Oil Company of California and Brea Agricultural Services, Inc. (collectively Union Oil) appeal from a judgment of the United States District Court for the Eastern District of California, No. CV-F-83-68 REC, entered on a jury verdict which declared U.S. Patent No. 4,310,343 ('343), owned by Verdegaal Brothers, Inc., "valid" and claims 1, 2, and 4 thereof infringed by Union Oil. Union Oil's motion for judgment notwithstanding the verdict (JNOV) was denied. We reverse.

I

BACKGROUND

The General Technology

The patent in suit relates to a process for making certain known urea-sulfuric acid liquid fertilizer products. These products are made by reacting water, urea (a nitrogen-containing chemical), and sulfuric acid (a sulfur-containing chemical) in particular proportions. The nomenclature commonly used by the fertilizer industry refers to these fertilizer products numerically according to the percentages by weight of four fertilizer constituents in the following order: nitrogen, phosphorous, potassium, and sulfur. Thus, for example, a fertilizer containing 28% nitrogen, no phosphorous or potassium, and 9% sulfur is expressed numerically as 28-0-0-9.

The Process of the '343 Patent

The process disclosed in the '343 patent involves the chemical reaction between urea and sulfuric acid, which is referred to as an exothermic reaction because it gives off heat. To prevent high temperature buildup, the reaction is conducted in the presence of a nonreactive, nutritive heat sink which will absorb the heat of reaction. Specifically, a previously-made batch of liquid fertilizer—known as a "heel"—can serve as the heat sink to which more reactants are added. Claims 1 and 2 are representative:

1. In a process for making a concentrated liquid fertilizer by reacting sulfuric acid and urea, to form an end product, the improvement comprising:
   a. providing a non-reactive, nutritive heat sink, capable of dissipating the heat of urea and sulfuric acid, in an amount at least 5% of the end product,
   b. adding water to the heat sink in an amount not greater than 15% of the end product,
   c. adding urea to the mixture in an amount of at least 50% of the total weight of the end product,
   d. adding concentrated sulfuric acid in an amount equal to at least 10% of the total weight of the end product.
2. The process of claim 1 wherein the heat sink is recycled liquid fertilizer.

Procedural History

Verdegaal brought suit against Union Oil in the United States District Court for the Eastern District of California charging that certain processes employed by Union Oil for making liquid fertilizer products infringed all claims of its '343 patent. Union Oil defended on the grounds of noninfringement and patent invalidity under 35 U.S.C. §§ 102, 103. The action was tried before a jury which returned a verdict consisting of answers to five questions. Pertinent here are its answers that the '343 patent was "valid" over the prior art, and that certain of Union Oil's processes infringed claims 1, 2, and 4 of the patent. None were found to infringe claims 3 or 5. Based on the jury's verdict, the district court entered judgment in favor of Verdegaal.

Having unsuccessfully moved for a directed verdict under Fed.R.Civ.P. 50(a), Union Oil timely filed a motion under Rule 50(b) for JNOV seeking a judgment that the claims of the '343 patent were invalid

under sections 102 and 103. The district court denied the motion without opinion.

II

ISSUE PRESENTED

Did the district court err in denying Union Oil's motion for JNOV with respect to the validity of claims 1, 2, and 4 of the '343 patent?

III

Standard of Review

[1] When considering a motion for JNOV a district court must: (1) consider all of the evidence; (2) in a light most favorable to the non-moving party; (3) drawing all reasonable inferences favorable to that party; (4) without determining credibility of the witnesses; and (5) without substituting its choice for that of the jury's in deciding between conflicting elements of the evidence. *Railroad Dynamics, Inc. v. A. Stucki Co.*, 727 F.2d 1506, 1512–13, 220 USPQ 929, 936 (Fed.Cir.), *cert. denied*, 469 U.S. 871, 105 S.Ct. 220, 83 L.Ed.2d 150 (1984); *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 1546, 220 USPQ 193, 197 (Fed.Cir.1983). A district court should grant a motion for JNOV only when it is convinced upon the record before the jury that reasonable persons could not have reached a verdict for the nonmoving party. *Railroad Dynamics*, 727 F.2d at 1513, 220 USPQ at 936; *Connell*, 722 F.2d at 1546, 220 USPQ at 197.

[2] To reverse the district court's denial of the motion for JNOV, Union Oil must convince us that either the jury's factual findings are not supported by substantial evidence, or, if they are, that those findings cannot support the legal conclusions which necessarily were drawn by the jury in forming its verdict. *See Perkin-Elmer Corp. v. Computervision Corp.*, 732 F.2d 888, 893, 221 USPQ 669, 673 (Fed.Cir.), *cert. denied*, 469 U.S. 857, 105 S.Ct. 187, 83 L.Ed.2d 120 (1984); *Railroad Dynamics*, 727 F.2d at 1512, 220 USPQ at 936. Substantial evidence is more than just a mere scintilla; it is such relevant evidence from the record taken as a whole as a reasonable mind might accept as adequate to support the finding under review. *Consolidated Edison Co. v. NLRB*, 305 U.S. 197, 229, 59 S.Ct. 206, 216, 83 L.Ed. 126 (1938); *Perkin-Elmer*, 732 F.2d at 893, 221 USPQ at 673; *SSIH Equip. S.A. v. U.S. Int'l Trade Comm'n*, 718 F.2d 365, 371 n. 10, 218 USPQ 678, 684 n. 10 (Fed.Cir.1983). A trial court's denial of a motion for JNOV must stand unless the evidence is of such quality and weight that reasonable and fair-minded persons in the exercise of impartial judgment could not reasonably return the jury's verdict. *Envirotech Corp. v. Al George, Inc.*, 730 F.2d 753, 758, 221 USPQ 473, 477 (Fed.Cir.1984).

[3] Our precedent holds that the presumption of validity afforded a U.S. patent by 35 U.S.C. § 282 requires that the party challenging validity prove the facts establishing invalidity by clear and convincing evidence. *American Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1360, 220 USPQ 763, 770 (Fed.Cir.), *cert. denied*, 469 U.S. 821, 105 S.Ct. 95, 83 L.Ed.2d 41 (1984). Thus, the precise question to be resolved in this case is whether Union Oil's evidence is so clear and convincing that reasonable jurors could only conclude that the claims in issue were invalid. *See Perkin-Elmer*, 732 F.2d at 893, 221 USPQ at 673; *Railroad Dynamics*, 727 F.2d at 1511, 220 USPQ at 935.

Anticipation

[4] A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *See, e.g., Structural Rubber Prods. Co. v. Park Rubber Co.*, 749 F.2d 707, 715, 223 USPQ 1264, 1270 (Fed.Cir.1984); *Connell*, 722 F.2d at 1548, 220 USPQ at 198; *Kalman v. Kimberly-Clark Corp.*, 713 F.2d 760, 771, 218 USPQ 781, 789 (Fed.Cir.1983), *cert. denied*, 465 U.S. 1026, 104 S.Ct. 1284, 79 L.Ed.2d 687 (1984). Union Oil asserts that the subject claims of the '343 patent

are anticipated under 35 U.S.C. § 102(e)[1] by the teachings found in the original application for U.S. Patent No. 4,315,763 to Stoller, which the jury was instructed was prior art.

[5] From the jury's verdict of patent validity, we must presume that the jury concluded that Union Oil failed to prove by clear and convincing evidence that claims 1, 2, and 4 were anticipated by the Stoller patent. *See Perkin-Elmer*, 732 F.2d at 893, 221 USPQ at 673; *Railroad Dynamics*, 727 F.2d at 1516, 220 USPQ at 939. Under the instructions of this case, this conclusion could have been reached only if the jury found that the Stoller patent did not disclose each and every element of the claimed inventions. Having reviewed the evidence, we conclude that substantial evidence does not support the jury's verdict, and, therefore, Union Oil's motion for JNOV on the grounds that the claims were anticipated should have been granted.

The Stoller patent discloses processes for making both urea-phosphoric acid and urea-sulfuric acid fertilizers. Example 8 of Stoller specifically details a process for making 30–0–0–10 urea-sulfuric acid products. There is no dispute that Example 8 meets elements b, c, and d of claim 1, specifically the steps of adding water in an amount not greater than 15% of the product, urea in an amount of at least 50% of the product, and concentrated sulfuric acid in an amount of at least 10% of the product. Verdegaal disputes that Stoller teaches element a, the step of claim 1 of "providing a non-reactive, nutritive heat sink." As set forth in claim 2, the heat sink is recycled fertilizer.[2]

The Stoller specification, beginning at column 7, line 30, discloses:

> Once a batch of liquid product has been made, it can be used as a base for further manufacture. This is done by placing the liquid in a stirred vessel of appropriate size, adding urea in sufficient quantity to double the size of the finished batch, adding any water required for the formulation, and slowly adding the sulfuric acid while stirring. Leaving a heel of liquid in the vessel permits further manufacture to be conducted in a stirred fluid mass.

This portion of the Stoller specification explicitly teaches that urea and sulfuric acid can be added to recycled fertilizer, i.e., a heel or base of previously-made product. Dr. Young, Union Oil's expert, so testified. Verdegaal presented no evidence to the contrary.

[6] Verdegaal first argues that Stoller does not anticipate because in Stoller's method sulfuric acid is added *slowly*, whereas the claimed process allows for rapid addition. However, there is no limitation in the subject claims with respect to the rate at which sulfuric acid is added, and, therefore, it is inappropriate for Verdegaal to rely on that distinction. *See SSIH*, 718 F.2d at 378, 218 USPQ at 689. It must be assumed that slow addition would not change the claimed process in any respect including the function of the recycled material as a heat sink.

[7] Verdegaal next argues that the testimony of Union Oil's experts with respect to what Stoller teaches could well have been discounted by the jury for bias. Discarding that testimony does not eliminate the reference itself as evidence or its uncontradicted disclosure that a base of recycled fertilizer in a process may be used to make more of the product.

[8] Verdegaal raises several variations of an argument, all of which focus on the

1. Section 102(e) provides:

> A person shall be entitled to a patent unless—
>
> ....
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent. ...

2. Claim 4 is written in terms of approximate percentages of all reactants by weight of the end product. No argument is made that the process of claim 4 would result in a fertilizer product any different from that disclosed by Example 8 of Stoller.

failure of Stoller to explicitly identify the heel in his process as a "heat sink." In essence, Verdegaal maintains that because Stoller did not recognize the "inventive concept" that the heel functioned as a heat sink, Stoller's process cannot anticipate. This argument is wrong as a matter of fact and law. Verdegaal's own expert, Dr. Bahme, admitted that Stoller discussed the problem of high temperature caused by the exothermic reaction, and that the heel could function as a heat sink.[3] In any event, Union Oil's burden of proof was limited to establishing that Stoller disclosed the same process. It did not have the additional burden of proving that Stoller recognized the heat sink capabilities of using a heel. Even assuming Stoller did not recognize that the heel of his process functioned as a heat sink, that property was inherently possessed by the heel in his disclosed process, and, thus, his process anticipates the claimed invention. *See In re Oelrich*, 666 F.2d 578, 581, 212 USPQ 323, 326 (CCPA 1981); *In re Swinehart*, 439 F.2d 210, 212–13, 169 USPQ 226, 229 (CCPA 1971). The pertinent issues are whether Stoller discloses the process of adding urea and sulfuric acid to a previously-made batch of product, and whether that base would in fact act as a heat sink. On the entirety of the record, these issues could only be resolved in the affirmative.

On appeal Verdegaal improperly attempts to attack the status of the Stoller patent as prior art, stating in its brief:

> Verdegaal also introduced evidence at trial that the Stoller patent is not prior art under 35 U.S.C. §§ 102(e)/103. Professor Chisum testified that the Stoller patent, in his opinion, was not prior art.... This conclusion finds support in *In re Wertheim*, 646 F.2d 527 (CCPA 1981), and 1 Chisum on Patents § 3.07[3].

Appellee Brief at 27 (record cite omitted). Seldom have we encountered such blatant distortion of the record. A question about the status of the Stoller disclosure as prior art did arise at trial. Union Oil asserted that, even though the Stoller patent issued after the '343 patent, Stoller was prior art under section 102(e) as of its filing date which was well before the filing date of Verdegaal's application. Professor Chisum never testified that the Stoller patent was *not* prior art, but rather, stated that *he did not know* whether it was prior art. An excerpt from the pertinent testimony leaves no doubt on this point:

> Q. (Mr. Sutton): And do you know whether the Stoller patent is prior art to the application of the Verdegaal patent?
>
> A. (Prof. Chisum): I don't know that it is, no.

We find it even more incredible that Verdegaal would attempt to raise an issue with respect to the status of the Stoller patent given that the case was submitted to the jury with the instruction that the original Stoller patent application was prior art.[4] Verdegaal made no objection to that instruction below, and in its appeal briefs, the instruction is cavalierly ignored.

In sum, Verdegaal is precluded from arguing that the Stoller patent should not be considered prior art. *See* Fed.R.Civ.P. 51; *Weinar v. Rollform Inc.*, 744 F.2d 797, 808, 223 USPQ 369, 375 (Fed.Cir.1984), *cert. denied*, 470 U.S. 1084, 105 S.Ct. 1844, 85 L.Ed.2d 143 (1985); *Bio-Rad Laboratories, Inc. v. Nicolet Instrument Corp.*, 739 F.2d 604, 615, 222 USPQ 654, 662 (Fed. Cir.), *cert. denied*, 469 U.S. 1038, 105 S.Ct. 516, 83 L.Ed.2d 405 (1984).[5]

3. There is no dispute that the percentage of heel described in Stoller meets the percentage of heat sink required by the claims.

4. The jury instruction read:
> Stoller filed two patent applications—an original application on October 30th, 1978, and a second on February 7th, 1980. Under the patent laws, the claims of the 343 patent are invalid if you find that the original application (Exhibit BL) anticipates the process claimed in the 343 patent.

5. Union Oil also argues that Verdegaal's counsel misled the jury by its closing rebuttal argument:
> [B]ut I think it's important to keep in mind that [Stoller] couldn't have been a prior patent because it issued a month after the Verdegaal patent had issued.

We disapprove of Verdegaal's tactic which would form the basis for a grant of a motion for a new trial but for our conclusion that outright reversal of the ruling on the motion for JNOV is in order.

After considering the record taken as a whole, we are convinced that Union Oil established anticipation of claims 1, 2, and 4 by clear and convincing evidence and that no reasonable juror could find otherwise. Consequently, the jury's verdict on validity is unsupported by substantial evidence and cannot stand. Thus, the district court's denial of Union Oil's motion for JNOV must be reversed.

Conclusion

Because the issues discussed above are dispositive of this case, we do not find it necessary to reach the other issues raised by Union Oil.[6] In accordance with this opinion, we reverse the portion of the judgment entered on the jury verdict upholding claims 1, 2, and 4 of the '343 patent as valid under section 102(e) and infringed.

REVERSED.

Richard J. SISSON, Appellee,

v.

The UNITED STATES, Appellant.

Appeal No. 86-1485.

United States Court of Appeals, Federal Circuit.

March 17, 1987.

Air Force master sergeant was court-martialed and convicted of charges that he violated Air Force regulation by making personal commercial solicitations of lower-ranking enlisted members and violated a command directive by engaging in outside commercial activity for compensation without approval of his immediate commanders. After exhausting military remedies, sergeant brought suit challenging the regulations. The United States District Court for the District of Arizona, Alfredo C. Marquez, J., 630 F.Supp. 1026, voided the court-martial, and Government appealed. The Court of Appeals, Davis, Circuit Judge, held that: (1) sergeant had proper notice that regulation prohibited group solicitations; (2) court-martial could permissibly find that sergeant also made one-on-one solicitations of lower ranking enlisted members; and (3) there was no violation of due process in applying directive to sergeant, even though directive was adopted after he became member of the military and began to engage in outside commercial activity, because sergeant should have known of directive, whether or not he had actual knowledge.

Reversed.

1. Constitutional Law ⇐278.6(2)

Air Force master sergeant who was court-martialed and convicted on charge that he violated Air Force regulation by making personnel commercial solicitations of lower-ranking enlisted members had fair notice that regulation prohibited group solicitations by a superior as well as one-on-one solicitations, and thus his conviction is not in violation of his constitutional rights; moreover, court-martial could have permissibly found that sergeant also made one-on-one solicitations.

2. Armed Services ⇐36

Constitutional Law ⇐278.6(2)

It was not a violation of due process to apply Air Force command directive requiring approval of immediate commanders before engaging in gainful outside activity to Air Force master sergeant, even though directive was adopted after sergeant became a member of the military and began to engage in commercial activities, and there was no showing that he knew about directive; there was sufficient evidence to find that sergeant should have known of

6. It should not be inferred that all of these issues were properly before us. Union Oil appears to assume that on appeal it may dispute the resolution of any *issue* which is denominated an "issue of law" even though it was not raised in its motion for JNOV. This is incorrect. *See Railroad Dynamics,* 727 F.2d at 1511, 220 USPQ at 934.

prerequisite, the fact and nature of the misconduct, is not at issue in this case. It cannot be held that every type of sex offense is a basis for removal from every position in the agency. 5 U.S.C. § 2302(b)(10) (1982) specifically prohibits discrimination against any employee "on the basis of conduct which does not adversely affect the performance of the employee . . . or the performance of others."

Even though there is nexus between Mr. Allred's off-duty conduct and the particular job-related responsibilities of the position from which he was removed, the efficiency of the service has been proved to require no more than that he be demoted to a level where he no longer interacts with outsiders. *See, e.g., White v. United States Postal Service*, 768 F.2d 334, 336 (Fed.Cir. 1985); *Brown v. Dept. of Transportation, FAA*, 735 F.2d 543, 548 (Fed.Cir.1984). Because of lack of proof of nexus to other positions for which Allred was qualified, there is no obstacle to imposition of a lesser penalty.

In view of the above, I would remand.

Milton HODOSH and Richardson-Vicks, Inc., Appellants,

v.

BLOCK DRUG COMPANY, INC., et al., Appellees.

Appeal No. 85-2607.

United States Court of Appeals, Federal Circuit.

March 24, 1986.

Owner and licensee of patent describing method of desensitizing teeth brought infringement action. The United States District Court for the District of New Jersey, H. Lee Sarokin, J., granted summary judgment to defendant, and plaintiffs appealed. The Court of Appeals, Rich, Circuit Judge, held that genuine issue of material fact existed with respect to meaning of various terms used in Chinese and European references, precluding summary judgment on ground of obviousness.

Reversed and remanded.

1. Patents ⇐16(2), 72

Whether a reference is available as prior art and whether it anticipates, i.e., contains every claimed element, are separate questions. 35 U.S.C.A. §§ 102, 102(b).

2. Patents ⇐323.2(2)

In infringement action brought by owner and licensee of patent describing method of desensitizing teeth, genuine issues of material fact existed with respect to meaning of various terms used in Chinese and European references, precluding summary judgment on ground of obviousness of the claimed invention. 35 U.S.C.A. § 103.

3. Patents ⇐36.1(1)

Evidence of secondary considerations is to be considered in patent infringement suit independently of what any real person knows about the prior art; these considerations are objective criteria of obviousness that help eliminate subjective determination involved in hypothesis used to draw legal conclusion of obviousness. 35 U.S.C.A. § 103.

John O. Tramontine, Fish & Neave, of New York City, argued for appellant, Richardson-Vicks, Inc.

Hugh A. Chapin, Kenyon & Kenyon of New York City, argued for appellant, Mil-

gitimately be a factor to be considered, I believe it has improperly been elevated in this case to the level of an offensive instrument by means of which a vague standard of morality has been interpolated between the lines of Title 5 of the United States Code. I doubt Congress so intended.

ton Hodosh. With them on the brief were W. Edward Bailey and Norman H. Beamer of Fish & Neave and Paul Lempel and William J. McNichol, Jr. of Kenyon & Kenyon.

Jerome G. Lee, Morgan, Finnegan, Pine, Foley & Lee, of New York City, argued for appellees. With him on brief were William S. Feiler and Maria C.H. Lin of Morgan, Finnegan, Pine, Foley & Lee, and Marvin C. Soffen and Edward A. Meilman, Ostrolenk, Faber, Gerb & Soffen.

Before RICH, DAVIS, and BALDWIN, Circuit Judges.

RICH, Circuit Judge.

This appeal is from the July 12, 1985, judgment of the United States District Court for the District of New Jersey, 226 USPQ 645, granting summary judgment to Block Drug Company, Inc., et al. (Block) and holding that all six claims of patent No. 3,863,006 for "Method of Desensitizing Teeth" ('006 patent), issued to Dr. Milton Hodosh and licensed to Richardson-Vicks, Inc. (collectively, Hodosh), are invalid for obviousness under 35 U.S.C. § 103. We reverse and remand.

Background

Tooth desensitizers reduce discomfort and pain caused by tooth hypersensitivity or exposed dentin, the portion of the tooth between the enamel and the pulp which includes a myriad of microscopic tubules. Persons suffering from this condition react painfully to hot or cold foods, citric acid or sweets, or everyday chemical, thermal, or tactile stimuli including toothbrush contact.

Milton Hodosh, a practicing dentist for about thirty years, independently developed the claimed subject matter of the '006 patent and granted Richardson-Vicks an exclusive license to make, use, and sell the claimed invention; the latter markets its tooth desensitizing toothpaste under the trademark "Denquel."

Claim 1 of the '006 patent [1] reads:

> The method of desensitizing hypersensitive dentin and cementum by applying thereto an agent the essential ingredient of which is a nitrate of one of the following alkali metals: potassium, lithium or sodium said nitrate comprising between 1 percent and 20 percent by weight of said agent.

The remaining claims appear in the opinion below.

Appellee Block has, since 1961, marketed a tooth desensitizing toothpaste, covered by its patent No. 2,122,483 (the Rosenthal patent) for "Strontium Ion Toothpaste" issued in 1964, under the trademark "Sensodyne." The Rosenthal patent and the '006 patent disclose toothpaste formulae which are the same except that the latter contains, as a desensitizing agent, potassium nitrate instead of the Rosenthal-Block strontium chloride. After requesting and being denied a license under the '006 patent, Block developed its own potassium nitrate-containing tooth-desensitizing toothpaste called "Promise" and "Sensodyne-F." [2]

March 30, 1983, Hodosh sued Block alleging that the sale of "Promise" and "Sensodyne-F" contributorily infringed and actively induced infringement of the '006 patent. Block answered and counterclaimed alleging patent misuse and consequent unenforceability of the '006 patent. On July 11, 1984, Block moved for summary judgment as to both misuse and patent invalidity. Oral argument was heard October 16, 1984, and decision was reserved. June 14, 1985,

1. A certificate of reexamination confirming the patentability of claims 1–6 of the '006 patent was issued June 21, 1983, as a result of Hodosh's request for reexamination in 1982. Only one of the prior art references involved here, the Rosenthal patent, infra, was considered in the reexamination.

2. Block also initiated regulatory proceedings designed to delay or prevent Richardson-Vicks' marketing of "Denquel." Block, having allegedly failed to comply with Food and Drug Administration (FDA) procedures before marketing "Promise" and "Sensodyne-F" in competitive response to Richardson-Vicks' introduction of "Denquel," is currently defending itself in forfeiture proceedings initiated by the FDA.

the reported decision was handed down granting the motion as to patent invalidity and dismissing the motion on misuse as moot, resulting in the judgment now on appeal.

The district court heard no expert testimony, but did hear arguments of counsel, receive briefs, review exhibits, and had before it declarations and affidavits from experts on both sides commenting on the eight prior art references involved here, including the Rosenthal patent. The court determined that there were no genuine issues of material fact and concluded as a matter of law that the claims of the '006 patent were invalid under § 103 because the Rosenthal patent disclosed each element claimed in the '006 patent except the potassium nitrate, which, in its view, was disclosed in two Chinese references, both based on ancient Chinese writings. The court also stated that six European references supported its conclusion of obviousness.

Because the appropriateness of summary judgment is determined on an analysis of the facts, *First National Bank of Arizona v. Cities Service Co.*, 391 U.S. 253, 88 S.Ct. 1575, 20 L.Ed.2d 569 (1968), and because everything about these references, as a whole, *see, e.g., Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1138, 227 USPQ 543, 547–48 (Fed.Cir.1985), is important to our determination, we review the record and lay out the relevant portions of the references in some detail.

A. *The Chinese References*

1. *The Grand Dictionary of Chinese Medicine and Drugs (The Grand Dictionary)*

The *Grand Dictionary*, published in Hong Kong in 1963 and written in Chinese, is based on ancient Chinese compilations assembled roughly 500 years ago from works of physicians going back 4000–5000 years. Only a portion of the 1963 Chinese text was before the court and is before us on appeal. For purposes of this litigation, that portion was translated into English by Block's translator, Roger Wei-Ming Tsao (Mr. Cao). Mr. Cao is a doctor of Chinese medicine and a bilingual tutor. Block's other expert, Dr. Stephen Wei, a professor of dentistry fluent in Chinese, concurred in that translation. The writings from which the *Grand Dictionary* was compiled are not in evidence nor are any earlier writings.

In a nutshell, the district court relied upon the *Grand Dictionary* because of its discussion of "xiao shi" to which the *Grand Dictionary* associates the name "niter" and the chemical composition KNO_3 and the ability to cure, inter alia, tooth pain. The court's opinion was that this reference teaches the use of xiao shi, which is the same as niter and is therefore the same as potassium nitrate, to cure tooth pain; thus, the teachings of the Rosenthal patent and the *Grand Dictionary* show that the '006 invention would have been obvious.

The following discussion and quotations are part of an attempt to convey the nature of the *Grand Dictionary*. The translated portion of the *Grand Dictionary* is entitled "Niter." The text under the first subheading "Nomenclature" reads: "It was so named because it has the power to consume various stones." Under "Other Names Stated in Classical Medical Books," the text reads "Mang Xiao (Bie-Lu), Bitter Xiao (Zhen-Quan), Flaming Xiao (Tu-Su) ... and Xiao-Shi ...." Thereafter, following "Foreign Names," the *Grand Dictionary* reads: "Salpetrae, Salnitri (in Latin); Niter (in English); and Salpoter (in German)." One page later, "KNO_3" is listed under "Chemical Composition."

The portion upon which Block and the district court rely to show that this substance cures tooth pain is headed "Collective Statements" and reads:

> (Ming): Li-Shi-Zhen said: It cures summer infections and the catching of colds. It cures acute enteritis with severe vomiting, exertion through excessive sexual activity, black jaundice, chronic abdominal pain, conjunctivitis, headaches and tooth pain.

The next three or so pages of the *Grand Dictionary* list the ailments that this substance cures. An interesting but not atypi-

cal paragraph reads: "For curing the paralysis of the four limbs, leprosy or problems caused by Taoist stone eating." This substance also apparently cures indigestion, lack of energy, typhoid, cataracts, and much, much more. The *Grand Dictionary* compares what appears to be various forms in which xiao shi is found, and the characteristics of each. An excerpt is:

> Pu-Xiao (Na_2SO_4) has the nature of water, tastes salty, and its flavor is cold. It can only descend and cannot ascend. It is Yin within Yin—that's why it can cleanse the accumulation in the gastrointestinal tract and can expel the San-Jiao devilish fire. Whereas Niter (KNO_3) has the nature of fire, tastes bitter and spicy, tastes slightly salty and has a flavor which is very warm, it's [sic] nature is ascending. It is fire within water. That's why it can break the accumulation and disperse hardness, and cure the febrile diseases.

2. *Ben Cao Gang Mu*

Ben Cao Gang Mu (Ben Cao) is a treatise on Chinese Medicine published in Hong Kong, in Chinese, in 1930, 1954, and 1965, but was originally written by Li-Shi-Zhen who lived during the Ming Dynasty.[3] Like the *Grand Dictionary*, only a portion of the Chinese text *Ben Cao* is in evidence and that portion was translated by Mr. Cao and Dr. Wei for purposes of this litigation. The district court relied upon *Ben Cao* because it discusses "xiao shi," which the translation of *Ben Cao* states is "niter" and associates the ability to cure "tooth pain (Ya Tong or Ya Teng)."

It is important to note, and the district court appeared to accept as fact, that the portion of the *Grand Dictionary* relied upon was compiled during the Ming Dynasty of the 13th to 15th centuries in *Ben Cao Gang Mu* so that the relevant portion of the *Grand Dictionary* is substantially a restatement of *Ben Cao* with some modification by an unidentified author. The court stated that these two references "quote the same Ming Dynasty source as labeling KNO_3 for tooth pain."

The *Ben Cao* translation is entitled "Xiao-Shi (Niter)" and refers to the same "Other names" for this substance listed in the *Grand Dictionary*. With respect to the quoted sections above, the *Ben Cao* translation is nearly verbatim. It has this to say about tooth pain:

> Da Ming states: It cures summer infections and the catching of colds; acute enteritis with severe vomiting, exertion thru excessive sexual activity and black jaundice, chronic abdominal pain, conjunctivitis, headache and tooth pain (Ya-Tong or Ya Teng).

Hodosh argues that summary judgment was inappropriate; issues of fact as to the meanings of xiao shi and ya tong remain because a skilled dental researcher would surely seek and obtain a complete translation of the *Grand Dictionary* and of the other ancient Chinese references and would read those references carefully. Hodosh also argues that the ancient references should be dismissed because a person skilled in the art would find them incredible and would regard them as a quagmire of medical and dental nonsense. It therefore takes issue with the court's holding quoted below which apparently precluded inquiry into the accuracy of the references by one skilled in the art:

> [A]ttacks upon the translation leading up to the prior art reference embodied in the *Grand Dictionary of Chinese Medicine and Drugs*, ... or upon Chinese medicine as a whole, ... are not here regarded as particularly pertinent, since they require skill beyond the scope of the "experienced researcher in ... dental fields ..."

Hodosh relies heavily on its expert's, Dr. Shklar's, testimony about the Chinese references: "[T]hey represent in modern terms, materials that are rarely comprehensible and frequently contradictory in their literal terms. The materials are largely

3. The Ming Dynasty (1368–1644 AD) was marked by the restoration of traditional institutions in China and the development of the arts, especially in porcelain, textiles, and painting.

seen by contemporary medical scientists as absurd; no serious medical researcher would waste his or her time with them." [4] Hodosh also contests this holding by the district court:

> Nor, if it is true that KNO_3 alleviates tooth sensitivity, is such reference in the prior art rebutted by the existence of errors in the reference such as, for example, the claim that KNO_3 is a cure for "exertion through excessive sexual activity." Whatever the merits of the other aspects of the Chinese references, the fact that they reveal KNO_3 to be a cure for ya tong is what is dispositive here. The reference clearly discloses such function of potassium nitrate, albeit in the context of otherwise incredible, and even erroneous descriptions of the compound's quality.

With respect to the specific meaning of xiao shi as used in these references, both Dr. Shklar and Hodosh's other expert, Mr. Yen, a professional translator of Chinese and English languages, stated that the compiler of the *Grand Dictionary* erred in associating potassium nitrate or niter with xiao shi. Mr. Yen states that he

> was not able to render one single precise version because various dictionaries contain different and even conflicting definitions. For example, *Source of Words*, a Chinese language dictionary, published by Commercial Press, Taiwan, which has editions dating back to 1915, defines "Xiao-Shi" as "Mang-Xiao" on page 1255, and under "Mang-Xiao" on page 1770, reference is made that "Mang-Xiao" is "Liu-Suen-Na," and on page 1523 "Liu-Suen-Na" is defined as sodium sulfate ($Na_2SO_4 10H_20$).

Mr. Yen also stated that "Xiao-Shi could be more than one material and that more than one material may be represented by the term 'Xiao-Shi'."

Dr. Shklar concurred:

> In my opinion, therefore, the answer to the question: What was "Xiao-Shi," is that it represented many different materials which cannot be identified with certainty.
>
> * * * * * *
>
> Thus, these Exhibits did not describe potassium nitrate to one skilled in the art any more than any of the hundreds of salts, ores and oxides that possess some of the enumerated properties.

In addition, Dr. Shklar stated: "It is insufficient to simply state, as the Block translator does, that 'Xiao-Shi' is 'niter,' and then cite a modern dictionary to 'establish' that 'niter' is potassium nitrate." With respect to both the *Grand Dictionary* and *Ben Cao*, he stated that "the translator appears to have inserted the term 'niter' into the text where the phrase 'consumer of stones' actually belongs."

Block's arguments, on the other hand, in part based on the short affidavit by Mr. Wei, substantially follow the district court's opinion. Block also challenges the competence of Hodosh's experts stating that they "either had no knowledge or training in the Chinese language or Chinese medicine or were unfamiliar with dentistry or medicine generally." Block also emphasizes that the Chinese references correctly disclose many of potassium nitrate's characteristics, like burning with a violet flame, useability for making signal fires and gun powder, and its water solubility; these three properties of xiao shi in the Chinese references definitely confirm, according to Block, that xiao shi is potassium nitrate, KNO_3.

B. *The European Prior Art*

This art is contained in six references and was not relied upon to any significant degree by Block or the district court. Hodosh scarcely mentions it on appeal, instead preferring to show the existence of genuine issues of material fact with respect to the Chinese references. After concluding that using potassium nitrate to cure tooth pain would have been obvious from Rosenthal in

4. Dr. Shklar is the Charles A. Brackett Professor of Oral Pathology at the Harvard School of Dental Medicine, and is an acclaimed expert in dentistry. He is also an expert on the history of dentistry and holds membership in the American Academy of the History of Dentistry.

view of the Chinese art, the court stated: "Such holding is strengthened by the European prior art which, while ambiguous because of the several conflicting definitions in the term 'niter,' at least suggest to one skilled in the art that potassium nitrate ought to be tried as a cure for tooth pain in general."

Block submitted no affidavits that addressed the substance of the European references. Hodosh's Dr. Shklar, on the other hand, stated why this art, part of the "humors, spirits and Alchemy of the Dark Ages" having whatever medicinal effect they did by virtue of their use of wine, opium, or other narcotic substances, would have been questioned by one skilled in the art. He specifically contends that Block's translation of "nitre" is erroneous: "it is common knowledge that these terms meant sodium carbonate and/or sodium carbonate-sodium bicarbonate mixture...."

To afford a glimpse of the nature of these references, an interesting and typical excerpt, one quoted by the district court, based upon a statement by the long since deceased French surgeon Guy de Chauliac reads that "a mixture of 'cuttlebone, small white sea shells, pumice, burnt stag's horn, *nitre*, alum, rock salt, burnt roots of iris, aristolochia, and reeds' could create an effective dentifrice." (District court's emphasis.) Three of the European references are based on that statement. The district court noted the others:

> Additionally, a 1693 treatise by the British Professor of Physics William Salmon states that nitrum "held in the Mouth ... immediately helps the Toothach, if burnt and used in a Dentifrice, it cleanses and whitens the Teeth." ... Similarly, a reference work by Hardianus a Mynsicht, translated into English in 1682, describes a mixture, including "nitre" as a "tincture for the toothache." ... Finally, Pliny the Elder, in his *Historie of the World, The Second Tome*, translated into English in 1601, describes the use of nitre to "easeth the toothach, if the mouth and gums be washed therwith," or if burned, as a dentifrice. [Reference to Exhibits omitted.]

With this description of both the Chinese and European references, and of what they represent as a whole, in hand, we consider the proper application of the *Graham* standards and their effect upon the propriety of summary judgment in this case. *See generally Graham v. John Deere Co.*, 383 U.S. 1, 17, 86 S.Ct. 684, 693–94, 15 L.Ed.2d 545 (1966); *Panduit Corp. v. Dennison Manufacturing Co.*, 774 F.2d 1082, 227 USPQ 337 (Fed.Cir.1985).

OPINION

A. *Summary Judgment*

Summary judgment, in patent as in other cases, is appropriate where there is no genuine issue of material fact, and the movant is entitled to judgment as a matter of law. *See Molinaro v. Fannon/Courier Corp.*, 745 F.2d 651, 653–54, 223 USPQ 706, 707 (Fed.Cir.1984). The movant bears the burden of demonstrating the absence of all genuine issues of material fact, and the district court must view the evidence in a light most favorable to the nonmoving party and draw all reasonable inferences in its favor. *See United States v. Diebold, Inc.*, 369 U.S. 654, 655, 82 S.Ct. 993, 994, 8 L.Ed.2d 176 (1962); *Palumbo v. Don-Joy Co.*, 762 F.2d 969, 973, 226 USPQ 5, 7 (Fed.Cir.1985). The party opposing summary judgment must show an evidentiary conflict on the record; mere denials or conclusory statements are not sufficient. *Barmag Barmer Maschinenfabrik AG v. Murata Machinery, Ltd.*, 731 F.2d 831, 836, 221 USPQ 561, 564 (Fed.Cir.1984). Summary judgment is authorized where it is quite clear what the truth is. *Sartor v. Arkansas Natural Gas Corp.*, 321 U.S. 620, 627, 64 S.Ct. 724, 728–29, 88 L.Ed. 967 (1944).

B. *The Issues Below*

The decision and opinion of the district court granting summary judgment dealt with two issues: the first was whether the '006 patent is invalid as anticipated under § 102(b), the court holding it is not;

and the second was whether the '006 patent is invalid for obviousness under § 103, the court holding that it is. Hodosh of course appeals the summary judgment with respect to only the issue on which it lost—obviousness—and Block has not appealed. Because we are remanding for trial, however, we will comment briefly on anticipation to make it clear that we deem that question to have been conclusively disposed of in this case and because it is closely related to the obviousness issue.

1. *Anticipation, § 102(b)*

We agree entirely with the district court's holding that the '006 patent is not invalid as anticipated because there is no issue of fact that none of the prior art references discloses every element of the claimed invention. This issue was, therefore, appropriately and properly disposed of by summary judgment.

[1] We do not agree, however, with some of the district court's remarks about anticipation, in particular, that the unavailability of the Chinese references and whether one skilled in the art could locate them with "reasonable diligence" bears on whether those references anticipate the claimed subject matter. Whether a reference is available as prior art and whether it anticipates (i.e., contains every claimed element) are separate questions. Moreover, the district court's determination that the references are unavailable for § 102 purposes seems to be inconsistent with the approach subsequently taken by the district court in determining obviousness. The court later used these same references to support its holding that the claimed subject matter would have been obvious at the time the invention was made to one of ordinary skill in the art.

2. *Obviousness, § 103*

[2] Questions of material fact remain with respect to the meaning of various terms used in the Chinese and European references and we therefore hold that summary judgment on the ground of obviousness of the claimed invention was improper.

The district court's statement that ya tong means tooth hypersensitivity as well as tooth pain is the resolution of a head-on factual controversy. The court improperly drew the inference against Hodosh, the nonmoving party, that a statement about ya tong made to the German Patent Office by Dr. Hodosh's German Patent Office by Dr. Hodosh's German patent agent was made with knowledge of the Chinese references. The statement in question occurred seven years after the '006 patent issued in connection with Dr. Hodosh's counterpart German application. The statement was: "The supersensitivity of dentine has been known for a long time and can be traced back 4000 years to the Chinese where it was known as 'Ya Tong'." Hodosh in this suit disclaims this statement urging that it was factual error.

There is no evidence that the above statement was based on the Chinese references or that Dr. Hodosh conveyed this information to the German patent agent. The important fact question as to the meaning of ya tong cannot be overcome simply by styling this statement an admission binding on Hodosh. Hodosh is entitled, as Block essentially concedes, to rebut the statement with evidence to the contrary. Hodosh will have that chance at trial.

Nor does the statement in the affidavit of Block's expert, Dr. Wei, that ya tong means tooth hypersensitivity eliminate the presence of the question of the meaning of ya tong. As the Supreme Court long ago observed, "Experience has shown that opposite opinions of persons professing to be experts, may be obtained to any amount ...." *Winans v. New York and Erie Railroad Co.*, 21 How. 88, 62 U.S. 88, 16 L.Ed. 68 (1859). The substance of Dr. Skhlar's affidavit on behalf of Hodosh goes far beyond merely denying that ya tong means tooth hypersensitivity and thus is more than adequate to show an evidentiary conflict on the record with respect to this crucial point, thus precluding summary judgment. *Cf. Union Carbide Corp. v. American Can Co.*, 724 F.2d 1567, 1571, 220 USPQ 584, 587–88 (Fed.Cir.1984).

Furthermore, a genuine issue of material fact exists with respect to the meaning of the terms nitre, nitrum, and nitri as used in the European references. Dr. Shklar's affidavit is more than adequate to withstand the challenge of this summary judgment motion. A reasonable inference that these terms are sodium, as opposed to potassium, compounds is permissible; Hodosh has shown an evidentiary conflict on the record. The European references, Dr. Shklar explained in his affidavit, are based on the 77 A.D. writings of Pliny The Elder, who understood these terms to mean "sodium carbonate and/or a sodium carbonate-sodium bicarbonate mixture."

The obviousness determination here, given the existence of genuine material issues of fact with respect to the meanings of terms used in these references, is not suitably disposed of by summary judgment under the rules pertaining thereto. *See generally Palumbo*, supra, and *Lemelson v. TRW, Inc.*, 760 F.2d 1254, 1260–61, 225 USPQ 697, 700–01 (Fed.Cir.1985). The fact issues herein must be resolved by trial in which the conflicting views of the experts will be subject to the refining fire of cross examination, a more effective means of arriving at the legal conclusion of obviousness vel non than perusal of ex parte affidavits and declarations of partisan experts lobbed at each other from opposing trenches.

We observe, for the benefit of the trial court, that we are totally unimpressed by Block's forensic device of comparing the Rosenthal prior art toothpaste formula and the Hodosh toothpaste example in parallel columns and then asserting, as though it were filled with significant meaning, that the "only difference is the use of potassium nitrate in place of strontium chloride," or that "the Hodosh patent merely substitutes potassium nitrate for strontium chloride." This device was pushed to the limit in oral argument by pointing out that the Hodosh toothpaste has the *same* formula, *except* for the active desensitizing ingredient, down to the last decimal point. This argument is meaningless on the obviousness issue. "Sensodyne" and apparently other desensitizing toothpaste formulae being well known as commercial products, it is entirely clear that Dr. Hodosh's invention was the discovery of an apparently superior *desensitizing agent* and he never thought it was a toothpaste formula. He made that invention even if it should later be decided that it was known to the Chinese. It is apparent that Hodosh's patent solicitor merely adopted the prior art Rosenthal toothpaste base formula as a convenient example to illustrate the kind of a paste in which the Hodosh desensitizer might be used, which was within his right. The similarities—indeed, identity—of the paste bases is irrelevant in considering the issue of the unobviousness of the desensitizer. The Rosenthal patent, cited as prior art by Hodosh in his patent specification, was the jumping-off place for the description of his discovery. Hodosh does not claim to have been the first inventor of a desensitizing toothpaste; he claims to have improved it. The issue for trial is whether his improvement would have been obvious.[5]

C. *Secondary Considerations*

[3] The district court refused on the motion for summary judgment to consider

5. Our comments on the district court's obviousness determination generally include the following tenets of patent law that must be adhered to when applying § 103: (1) the claimed invention must be considered as a whole (35 U.S.C. § 103; *see, e.g., Jones v. Hardy*, 727 F.2d 1524, 1529, 220 USPQ 1021, 1024 (Fed.Cir.1984) (though the difference between claimed invention and prior art may seem slight, it may also have been the key to advancement of the art)); (2) the references must be considered as a whole and suggest the desirability and thus the obviousness of making the combination (*see, e.g., Lindemann Maschinenfabrik GmbH v. American Hoist and Derrick Co.*, 730 F.2d 1452, 1462, 221 USPQ 481, 488 (Fed.Cir.1984)); (3) the references must be viewed without the benefit of hindsight vision afforded by the claimed invention (*e.g., W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1553, 220 USPQ 303, 313 (Fed.Cir.1983)); (4) "ought to be tried" is not the standard with which obviousness is determined (*Jones*, supra, 727 F.2d at 1530, 220 USPQ at 1026); and (5) the presumption of validity remains constant and intact throughout litigation (35 U.S.C. § 285; *e.g., American Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1359–60, 220 USPQ 763, 770 (Fed.Cir.1984)).

the evidence of secondary considerations. After acknowledging its existence and the arguments based on it, it stated:

> However, the court continues to find that the Hodosh patent is invalid on grounds of obviousness; these secondary considerations stem not from the novelty or inventiveness engendered by substituting potassium nitrate in an already existing formula, but from a lack of knowledge on the part of those in the field of the references here cited. That lack is here overcome by the presumption of omniscience discussed, *supra*, a rule of law by which the court is bound, whatever its merits.

That secondary considerations are not considered unless there is evidence that those in the industry knew of the prior art is a non sequitur. Evidence of secondary considerations is considered independently of what any real person *knows* about the prior art. These considerations are *objective* criteria of obviousness that help illuminate the subjective determination involved in the hypothesis used to draw the legal conclusion of obviousness based upon the first three factual inquiries delineated in *Graham*. Thus, to require that actual inventors in the field have the omniscience of the hypothetical person in the art is not only contrary to case law, *see Kimberly-Clark v. Johnson & Johnson*, 745 F.2d 1437, 223 USPQ 603 (Fed.Cir.1984), but eliminates a useful tool for trial judges faced with a nonobviousness determination.

The secondary consideration evidence of record and the additional evidence likely to be submitted at trial must be considered in the obviousness determination. *See generally Fromson v. Advance Offset Plate, Inc.*, 755 F.2d 1549, 1557, 225 USPQ 26, 32 (Fed.Cir.1985).

Conclusion

The grant of summary judgment of invalidity is *reversed* and the case is *remanded* for trial in accordance with this opinion.

REVERSED AND REMANDED.

MAST INDUSTRIES, INC., Appellee,

v.

The UNITED STATES, Appellant.

Appeal No. 86-676.

United States Court of Appeals, Federal Circuit.

April 1, 1986.

Appealed from U.S. Court of International Trade; DiCarlo, Judge.

Veronica A. Perry, Civ. Div., Dept. of Justice, New York City, argued, for appellant. With her on brief, were Richard K. Willard, Asst. Atty. Gen., David Cohen, Director and Joseph I. Liebman, Atty. in Charge, Intern. Trade Field Office.

Michael P. Maxwell, Greenfield, Desiderio, Lebowitz & Silverman, New York City, argued, for appellee. With him on brief, was Steven P. Florsheim.

Before BALDWIN, NIES, and ARCHER, Circuit Judges.

BALDWIN, Circuit Judge.

This appeal is from a decision of the United States Court of International Trade holding that a sleepshirt was designed, manufactured, marketed, and used as nightwear, and an order directing the U.S. Customs Service to permit entry of the merchandise under Item 384.5226 of the Tariff Schedules of the United States.

Appellant's arguments are adequately treated in the lower court's opinion No. 85-114, dated October 28, 1985. We affirm on the basis of that opinion.

AFFIRMED.

Application of Stephen F. ROYKA and Robert G. Martin.
Patent Appeal No. 9092.

United States Court of Customs and Patent Appeals.
Feb. 7, 1974.

Appeal from the decision of the Patent Office Board of Appeals affirming the examiner's rejection of patent application, Serial No. 648,701, for a "responsive answer system." The Court of Customs and Patent Appeals, Rich, J., held that an answer sheet for use in self-instruction and testing, in which were printed in "response areas" meaningful information in permanent printing and confusing information in printing which could be removed, as by an erasure, both being legible so that a student, seeing a choice of answers to a question, was required to make a selection, the correctness of the selection being shown by the information which was then removed by the erasure, was not anticipated by prior patents and was therefore patentable.

Reversed.

Patents ⇐66(1.20)

"Responsive answer system," answer sheet for use in self-instruction and testing, in which were printed in "response areas" meaningful information in permanent printing and confusing information in printing which could be removed, as by erasure, both being legible so that student, seeing choice of answers to question, was required to make selection, correctness of selection being shown by information which was then removed by erasure, was not anticipated by prior patents and was therefore patentable. 35 U.S.C.A. §§ 102, 103.

Michael H. Shanahan, Rochester, N. Y., of record, for appellant; Thomas M. Webster, Rochester, N. Y., Boris Haskell, Washington, D. C. (Paris, Haskell & Levine), Washington, D. C., of counsel.

Joseph F. Nakamura, Washington, D. C., for the Commissioner of Patents. Fred W. Sherling, Washington, D. C., of counsel.

Before MARKEY, Chief Judge, and RICH, BALDWIN, LANE and MILLER, Judges.

RICH, Judge.

This appeal is from the decision of the Patent Office Board of Appeals affirming the examiner's rejection of claims 28 and 30–36 of application serial No. 648,701, filed June 26, 1967, entitled "Responsive Answer System." We reverse.

The Invention

The appealed claims are directed to a device in the nature of an answer sheet for use in self-instruction and testing. The answer sheet may be associated with questions or separate therefrom. The essential features of the invention are that there are printed on the answer sheet in "response areas" meaningful information in permanent printing and confusing information in printing which can be removed, as by an eraser, both being legible so that a student, seeing a choice of answers to a question, must make a selection. Having made a selection, he then applies an eraser to the selected response area and some of the information will be readily removed. What remains advises him of the correctness or otherwise of his answer. The following figures from the drawings are illustrative:

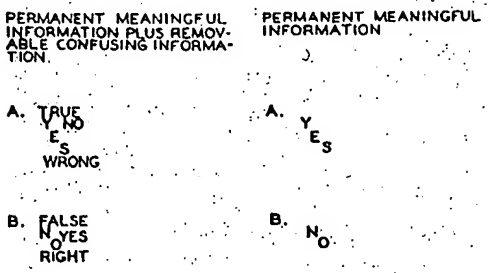


FIG. 1A FIG. 1B

Fig. 1A shows two response areas to a given question before any removing ac-

tion by the student has taken place and Fig. 1B shows the permanent information remaining in each after erasure of the removable information. Of course, if the student makes an initial choice of area A, showing up "YES" or some other indication of a correct answer, he will not need to proceed further and erase the B area. In a modified form of the invention, a wrong selection, plus erasure, may expose, instead of or in addition to a statement that the answer is wrong, a number or other reference to further material which is to be studied.

A preferred method of printing the permanent meaningful information and the removable confusing information is by that type of xerography in which a fusible toner is used, the permanence of the printing depending on the extent to which the toner image is "fixed" or fused by heat. By successive printings of the two kinds of information with fixing to different degrees, one image can be made permanent and the other made subject to easy removal, both images retaining such similarity of appearance that the user of the answer sheet cannot tell them apart.

Claim 28 is the principal claim, all others being dependent thereon, and reads as follows:

> 28. A device for selectively indicating information comprising
>
> a support having response areas for presenting information for selection,
>
> permanent printing indicative of meaningful information permanently fixed to said support within a response area, and
>
> removable printing indicative of confusing information removably fixed to said support within a response area,
>
> said meaningful and confusing information being substantially legible even when said permanent and removable printing are fixed over one another on said support,
>
> said permanent and removable printing being substantially similar such that an observer cannot determine which information is permanent and which is removable
>
> whereby the information within a response area is selected by attempting to remove the printing therein with the failure to remove printing identifying meaningful information.

Claims 30–36 add limitations which need not be considered except for noting that claims 33 and 34 alone specify the use of a xerographic toner, for which reason they were rejected on a different ground from the other claims.

The Rejection

The following references were relied on:

Reid et al. (Reid)	356,695	Jan. 25, 1887
Bernstein et al. (Bernstein)	3,055,117	Sep. 25, 1962
Lein et al. (Lein)	3,364,857 (filed Feb. 2, 1966)	Jan. 23, 1968

Claims 28, 30, 31, and 32 were rejected as anticipated under 35 U.S.C. § 102 by Bernstein; claims 28, 31, 32, 35, and 36 were rejected as anticipated under § 102 by Reid; and claims 33 and 34 were rejected under 35 U.S.C. § 103 for obviousness, on either Bernstein or Reid in view of Lein. These were the examiner's rejections and the board affirmed them, adhering to its decision on reconsideration.

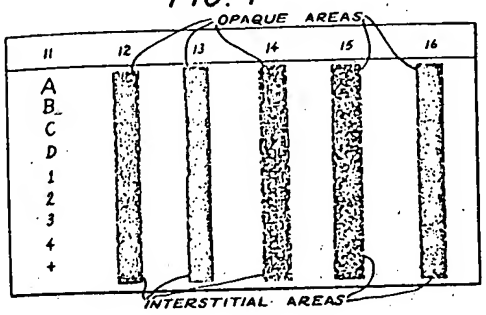
Bernstein discloses an answer sheet in which printed information representing a response is "temporarily concealed from the observer" and he discloses a number of different ways of effectively concealing the response. His specification states:

> The objects of the invention are accomplished by utilizing the hiding media to confuse the participant and to render the response and the hiding media indistinguishable and thus conceal the presence, absence, nature or position of the response from the participant. This may be effectuated by careful attention being paid to a number of factors including the design,

color and position of the hiding or confusing media.

Fig. 1 of Bernstein's drawings, illustrates some of his concealing means:

FIG. 1



The following is the written description:

> Referring now to the drawing, FIG. 1 illustrates some of the many optically confusing patterns which may be positioned between the printed structure to be concealed and the point of observation. Column 11 shows the information which is to be concealed. This information is repeated in columns 12 through 16 but in each case is concealed by a pattern in accordance with the present invention. Column 12 utilizes a pattern comprising an alphabetical maze in both line and half tone screen. Column 13 utilizes a pattern comprising an absorbing field having a plurality of irregular dot-like interstices. Column 14 utilizes a pattern comprising a maze of plus signs combined with dots. Columns 15 and 16 illustrate irregular and non-repetitious patterns.

Bernstein says that if at least 50% of the response is actually covered by the opaque portions of the confusion pattern, complete concealment is obtained. He also says that added means of concealment may be used, such as scoring and embossing and perforating the paper in order to scatter the light or let it shine through.

Reid is entitled "Transformation Picture and Print." The invention is said to be useful for advertisements, Christmas cards, birthday cards, valentines, and the like and as a source of amusement and instruction for children. It consists of a picture or print, part of which is permanently printed and part of which is removable from the paper on which it is printed. For the latter various soluble undercoatings or inks are described. If the picture is washed with a solvent, which may be water, the removable part disappears and the pictorial and/or typographic matter changes. The invention is illustrated by a typical nineteenth century temperance propaganda piece depicting the evils of drink. In the finished picture there are three scenes from left to right: Scene 1, the innocent child leads her father home from the pub; Scene 2, Father sits slumped in the kitchen chair with his bottle beside him, the family wash hanging above his head, this picture being entitled "The Effects of Drink"; Scene 3, Mother stands in front of a sign reading "Pawn Shop." Across the bottom of the picture is a legend which says "Wash the above and see what water will do." Fig. II shows the result of washing with water: Scene 1, a handsome young man and his happy daughter stroll on the street; Scene 2, Father sits erect in a well-appointed room at a cloth-covered table, apparently having a cup of tea, obviously a gentleman; Scene 3, Mother beams from the sideline and the Pawn Shop sign has vanished. Two new subscriptions appear and the words "The" and "Drink" have disappeared, the resultant being a new picture title reading "The Beneficial Effects of Temperance." "The Beneficial" and "Temperance" were covered by some soluble opaque in the original picture. No doubt the overall effect is instruction. Perhaps there was amusement in bringing about the transformation.

Lein relates to xerography and is relied on only for its disclosure of the removability of partially fused toner and the permanence of fully fused toner.

OPINION

As to the § 102 anticipation rejections, it will suffice to consider independent claim 28. If it is not fully met by Reid

or Bernstein, neither are the more limited dependent claims. It is elementary that to support an anticipation rejection, all elements of the claim must be found in the reference. We do not find claim 28 anticipated by Bernstein because, as we read the claim, it requires the display of *legible* meaningful and *legible* confusing *information* simultaneously, between which the user of the device may make a selection before he undertakes to remove any of the information from the response area selected by him. The element we find most clearly missing, contrary to the reasoning of the examiner and the board, is the legible confusing *information*. The Patent Office proposes to read this limitation on Bernstein's confusion patterns which are nothing but meaningless obscuring screens, conveying no information and providing the user with no basis for making a *selection*, as called for by claim 28. In appellants' device the legible confusing information—i. e., the wrong answers—are legible in the sense that they can be read as intelligible words, not merely a jumble of type serving to obscure the words of the wrong answers.

Appellants were fully aware of Bernstein and discussed its disclosures in their specification, distinguishing from this and other prior art, saying, in part:

> The inventive concept hereof confuses not by physical blocking as taught by the prior art, but by compounding, associating (including disarranging) permanent information with confusing information, usually at least some of which is similar in character to the permanent information as to render it impossible to tell which is permanent and which is removable confusing information. In the invention, generally no attempt is made to de-designedly physically cover the permanent information, but to confuse it beyond interpretation by the presentation of extraneous removable, confusing information.

Claims are not to be read in a vacuum and while it is true they are to be given the broadest *reasonable* interpretation during prosecution, their terms still have to be given the meaning called for by the specification of which they form a part. We cannot read the terms "legible" and "information" on Bernstein's confusion patterns, as did the examiner and the board. They are not "legible," as appellants use the term, and they convey no information.

As to anticipation by Reid, we find neither appellants' basic concept nor the substance of claim 28 to be disclosed. Apparently the solicitor could find little to support the rejection in Reid for all he says in his brief—so far as claim 28 is concerned—is:

> Reid discloses a sheet which may be used for instruction and which may have a removable design partly covering a fixed design * * *. Therefore, the disclosure of the reference encompasses the arrangement wherein a removable design covers a fixed design with both designs being substantially legible.

But claim 28 does not call for an arrangement wherein a removable design covers a fixed design. It calls for response areas, which Reid does not have, containing meaningful information in permanent printing together with removable printing conveying confusing information, both legible at the same time, between which a "selection" can be made. The only choice offered to the user by Reid is to follow the instruction to wash the whole visible picture with water or other solvent, thus removing the overprinting, to discover what the permanent picture is. The Patent Office attempt to read claim 28 on this reference is a tour deforce. We hold that Reid does not anticipate for failure to meet the limitations of claim 28 to "response areas," to the presentation of two categories of information (meaningful-permanent and removable-confusing) within such areas, and the possibility of selection. Anticipation requires a finding that the claimed invention be disclosed. It is not enough to say that appellants' invention and the reference are

both usable for instruction and both consist of permanent and removable printings on paper, as did the solicitor.

The dependent claims rejected with claim 28, as anticipated under § 102, are not anticipated since claim 28 is not anticipated. Some of them merely add features which are disclosed by the references and some do not. Insofar as they do not, they further negative anticipation. The examiner recognized this fact as to claims 33 and 34, which are limited to xerography, and therefore did not reject them under § 102. Similarly, he did not reject claim 30 on Reid or claims 35 and 36 on Bernstein. We find that claims 35 and 36 contain limitations which additionally distinguish from Reid. We have already noted that Reid has no "response areas" as required by claim 28 and so Reid does not disclose the structure of claim 35 which additionally requires both the correct and incorrect answers to appear within the same response area.

As to claim 36, the examiner said it "is merely a printed matter variation of the design of the reference," Reid. This is not a valid reason for rejection. Printed matter may very well constitute structural limitations upon which patentability can be predicated. We have commented on this matter In re Jones, 373 F.2d 1007, 54 CCPA 1218 (1967); and In re Miller, 418 F.2d 1392, 57 CCPA 809 (1969), and will not repeat ourselves. The limitations of claim 36 are not remotely suggested by Reid.

There remains the § 103 rejection of claims 33 and 34. Do they, taken together with all of the limitations of claim 28 from which they depend, define obvious subject matter? The difference between claim 28 and these two dependent claims is that they add the limitations to xerography. If Bernstein and Reid showed the claimed invention except for xerography, the addition of the Lein reference would make the subject matter of the claims obvious. But that is not the situation here. Adding the knowledge of xerographic technology to Bernstein or Reid still does not make the invention of claims 33 and 34 obvious for the same reasons we have given above in discussing anticipation. The essence of appellants' invention, as set forth in claim 28, is still missing notwithstanding the addition of the Lein reference and we see nothing in the combinations of references which would have made the invention obvious to one of ordinary skill in the art at the time it was made. We will, therefore, reverse this rejection.

The decision of the board is *reversed*.

Reversed.

CHRYSLER CORPORATION, Plaintiff-Appellant,

v.

John T. DUNLOP, Director Cost of Living Council, et al., Defendants-Appellees.

No. DC-18.

Temporary Emergency Court of Appeals.

Dec. 5, 1973.

In manufacturer's action for declaratory and injunctive relief with respect to order of the Cost of Living Council deferring consideration of the merits of manufacturer's proposed price increase, the United States District Court for the District of Columbia, Barrington D. Parker, J., denied preliminary injunction, and manufacturer appealed. The Temporary Emergency Court of Appeals held that if the order was not supported by substantial evidence, manufacturer would have substantial likelihood of prevailing on the merits, that the trial court should have made findings of fact and conclusions of law on the question of whether the order was supported by substantial evidence, and that the trial court should consider manufacturer's proposal that it would escrow all moneys

capital stock taxes, transportation taxes, or any State and local taxes. (The treatment of State and local real and personal property taxes are covered in Article XIX, paragraph 33, of the Housing Contract.)

(d) The eligible builder shall promptly notify the Contracting Officer of all matters pertaining to Federal taxes that reasonably may result in either an increase or decrease in the contract price. The eligible builder shall take action as directed by the Contracting Officer, and the contract price shall be equitably adjusted to cover the cost of such action, including any interest, penalty, and reasonable attorney's fees, such adjustment to be processed as a change order.

57 CCPA

Application of David W. WILSON.

Patent Appeal No. 8271.

United States Court of Customs and Patent Appeals.

May 7, 1970.

Proceeding on patent application serial No. 332,321. The Patent Office Board of Appeals affirmed rejection of claims 1–4, 8–10, and 15–21, and applicant appealed. The Court of Customs and Patent Appeals, Lane, J., held that Patent Office Board of Appeals' disregard of term "incompatible" as used in claims relating to treatment of power driven rotary brushes with "incompatible" resins rendered its conclusion of obviousness unsupported.

Reversed.

1. Patents ⇐101(5)

Specification with respect to composition for treatment of power driven rotary brushes was sufficient to support claims in issue. 35 U.S.C.A. § 112.

2. Patents ⇐51(1)

All words in claim must be considered in judging patentability of claim against prior art. 35 U.S.C.A. § 103.

3. Patents ⇐18, 101(6)

If no reasonably definite meaning can be ascribed to certain terms in claim, subject matter does not become obvious, but claim becomes indefinite. 35 U.S.C.A. § 103.

4. Patents ⇐113(6)

Patent Office Board of Appeals' disregard of term "incompatible" as used in claims relating to treatment of power driven rotary brushes with "incompatible" resins rendered its conclusion of obviousness unsupported. 35 U.S.C.A. § 103.

Oberlin, Maky, Donnelly & Renner, William E. Thomson, Jr., John C. Oberlin, Cleveland, Ohio, attorneys of record, for appellant.

Joseph Schimmel, Washington, D. C., for the Commissioner of Patents. Raymond E. Martin, Washington, D. C., of counsel.

Before RICH, Acting Chief Judge, ALMOND, BALDWIN and LANE, Judges, and FORD, Judge, United States Customs Court, sitting by designation.

LANE, Judge.

This appeal is from the decision of the Patent Office Board of Appeals, which affirmed the rejection of claims 1–4, 8–10, and 15–21 in appellant's application serial No. 332,321, filed November 5, 1963, for "Treated Brush and Brush Treating Composition." Four other claims have been allowed. We conclude that the board's decision must be reversed.

THE DISCLOSURE

Appellant's disclosure discusses certain problems in the treatment of power-driven rotary brushes. According to the disclosure, it was desirable to pro-

duce a composition for treating the brush bristles, whereby the ability of the bristles to hold abrasive particles would be enhanced. It discloses that the treatment composition should have a strength of adhesion to the brush bristles sufficiently great to prevent such composition from transferring excessively to the object being brushed; that the treatment material should wear at substantially the same rate as the brush bristles; that the material should have a high temperature softening point; and that the strength of adhesion between the treating composition and the abrasive particles must be sufficient to withstand the centrifugal force which normally would tend to throw the abrasive outwardly from the brush. The disclosure states that previously known brush-treating compositions did not accomplish all these objectives and had a tendency to dry and lose their tackiness over a period of time, thus becoming useless for holding abrasive particles on the bristles.

The disclosure states that appellant discovered that a composition having a high temperature softening point and a high degree of tackiness could be produced if a film-forming resin were blended with a tackifier resin which was incompatible with (insoluble in) the film-forming resin. The resulting composition would have two distinct phases: a continuous phase comprised of film-forming resin, either alone or saturated with a small quantity of tackifier resin, and a dispersed phase comprised of small particles of tackifier resin. The two resins may be either completely or partially incompatible, and the disclosure states that the more insoluble the resins, the greater the tack which the composition possesses. Appellant also disclosed that certain plasticizers could be added to render the resins more incompatible, thus further increasing the tack of the composition. Finally, appellant stated that the entire composition could be dissolved in a volatile solvent to allow easy application to the brush, the solvent being one which quickly evaporates upon such application.

The specification contains a list of suitable film-forming resins, including ethyl cellulose, nitro cellulose, cellulose acetate, polyvinyl acetate and cis-polyisoprene, among other materials. A list of tackifiers is given, including certain esters of abietic acid, polyvinyl ethyl ether, coumarone indene resin and terpene resins. A list of plasticizers is also given. The specification then gives four examples showing how to combine various film-formers, tackifiers, plasticizers and solvents to obtain brush-treating compositions of the desired characteristics, and explains how to apply them to brushes.

THE CLAIMS

In view of the result we reach, we find that claims 1 and 8 are representative:

1. A two-phase brush treating composition having a high softening point and sufficient tack to retain abrasive material firmly adhered to brush fill material comprising a film-forming resin and a tackifier resin which is incompatible with said film-forming resin, said two phases comprising a continuous phase formed of said film-forming resin and a dispersed phase formed of small particles of tackifier resin.

8. In combination, a rotary brush having brush fill material and a two-phase pressure sensitive adhesive brush treating composition adhered thereto having a high softening point and sufficient tack to retain abrasive material firmly adhered to such brush fill material comprising a film-forming resin and a tackifier resin which is incompatible with said film-forming resin, said two phases comprising a continuous phase formed of said film-forming resin and a dispersed phase formed of small particles of tackifier resin.

The remaining claims on appeal are narrower, containing recitations of specific resins, plasticizers, etc.

THE PRIOR ART

Grantham[1] relates to coatings for film material and discloses a coating composition comprising a cellulose derivative film-former, a blending resin, a plasticizer, and an organic solvent. Grantham teaches that the blending agent and the film-former should be compatible.

Depew[2] teaches the preparation of emulsions consisting of a continouous phase of water and a discontinuous phase of elastomer particles and particles of a volatile hydrocarbon, with vulcanizing ingredients and other additives dispersed in the hydrocarbon particles. Depew then states that where a dispersion with additional adhesive properties is desired, an adhesive, such as certain of the tackifier resins disclosed by appellants, can be added to the emulsion, and that

> [t]his adhesive can be water soluble or dispersed as particles. * * * The chemistry of the adhesive component is not critical to this invention. The important thing is that the deposited film shall be tacky and adhesive.

Sergi[3] relates to adhesives suitable for installation of floor-covering products such as linoleum. Sergi's composition consists of a tackifier resin dispersed in a latex binder; the tackifier and latex must be compatible with one another, according to the Sergi disclosure.

Vaughan[4] teaches impregnating a fibrous buffing wheel with an aqueous emulsion consisting of a tacky resin and an emulsifier or stabilizer such as glue or gum.

THE BOARD

The board found the composition claims to be unpatentable over Depew, Sergi or Grantham under 35 U.S.C. § 103. The board reached this conclusion after noting that each of the three references shows some of the film-formers, tackifiers, plasticizers and solvents appearing in appellant's lists. The board found that the recited limitation of incompatibility was too relative a term to distinguish over the compositions of the references.

The board found that the claims to the treated brush were unpatentable, under 35 U.S.C. § 103, over Vaughan in view of Sergi or Depew. Since Vaughan shows treating brushes, the board apparently considered it obvious to treat brushes with compositions which it thought were made obvious by Sergi or Depew.

The board also affirmed the rejection of certain claims for being "broader than the disclosure" under 35 U.S.C. § 112. The board's basis for this rejection was that the specification did not provide adequate guidelines for making a selection among the various disclosed ingredients, nor among other materials which are not disclosed but would be included by the claims.

OPINION

[1] We first treat the rejection under section 112. This rejection is in effect an attack on the specification as being insufficient to teach how to practice the broad invention claimed. The rejection is therefore under the first paragraph of section 112. The board's position, as mentioned above, was that the specification did not teach how to select ingredients so that the desired incompatibility would result. We disagree with the board's position on this point. First of all, appellant provided four examples, each specifying the nature and amounts of materials to be used. Secondly, the record indicates that it involves only routine experimentation to find out which resins are incompatible. The examiner admitted as much when,

1. U.S.Pat. 3,051,670, issued August 28, 1962.
2. U.S.Pat. 2,933,469, issued April 19, 1960.
3. U.S.Pat. 3,015,638, issued January 2, 1962.
4. U.S.Pat. 2,890,136, issued June 9, 1959.

with regard to obviousness, he said "selecting the proper tackifier and film-forming resin from those listed in the references to form an emulsion or two-phase composition would be within the expected skill of the art and would merely involve routine experimentation." We conclude that appellant has provided a sufficient specification to support the claims here in issue.

[2–4] Turning to the rejection of the claims for obviousness, we again disagree with the board's position. The board has disregarded the term "incompatible," as used in the claims, because it is "too relative" to distinguish over the compositions of the references. Appellant contends this limitation is essential in defining his invention. There has been no rejection here for indefiniteness, under the second paragraph of section 112. Rather than reject the claims as indefinite, the board chose to ignore the language it considered indefinite, and proceeded as though that language were not in the claims. The board said, in effect, that since we do not know what "incompatible" means, and the rest of the claim defines obvious subject matter, there is no basis for concluding unobviousness. This reasoning is incorrect. All words in a claim must be considered in judging the patentability of that claim against the prior art. If no reasonably definite meaning can be ascribed to certain terms in the claim, the subject matter does not become obvious—the claim becomes indefinite. In the present case, we think the term "incompatible" is defined with reasonable definiteness in the specification. While it is true that the word is not perfectly precise, under the circumstances of the present case there appears to be no other way for appellant to describe his discovery. In any event, the ignoring of this term by the board renders its conclusion of obviousness unsupported. None of the references discloses a two-phase composition of incompatible resins or suggests that such a composition would have the properties disclosed by appellant. Grantham and Sergi both expressly teach that the components of their compositions should be compatible. Neither Vaughan nor Depew uses a resin as the continuous phase. While Depew states, as quoted above, that the adhesive material may be dispersed as particles in the continuous phase, and hence be incompatible with the continuous phase material, it cannot be ignored that Depew's continuous phase is of water, not a film-forming resin as recited in appellant's claims. Furthermore, there is no suggestion in Depew or Vaughan that there are advantages in using an adhesive which is insoluble in the aqueous phase. There is nothing of record, therefore, from which we can properly conclude that the subject matter of appellant's claims would have been obvious at the time of his invention. The decision of the board must accordingly be reversed.

Reversed.

57 CCPA

COSMETICALLY YOURS, INC., Appellant,

v.

CLAIROL INCORPORATED, Appellee.

Patent Appeal No. 8296.

United States Court of Customs and Patent Appeals.

May 7, 1970.

Appeal from decision of the Trademark Trial and Appeal Board, Opposition No. 44,363, sustaining an opposition to the application by appellant to the registration of the words "Look Alive" as a trademark for "lipstick". The Court of Customs and Patent Appeals, Rosenstein, J., held that absent a counterclaim for cancellation, it was not open to applicant to prove abandonment of opposer's registered "Come Alive" mark;

Intellectual Property Library ISSN 1526-8535

FULL TEXT OF CASES (USPQ2D)
All Other Cases

In re Wands (CA FC) 8 USPQ2d 1400 In re Wands

U.S. Court of Appeals Federal Circuit
8 USPQ2d 1400

Decided September 30, 1988
No. 87-1454

Headnotes

PATENTS

1. Patentability/Validity -- Adequacy of disclosure (§ 115.12)

Data disclosed in application for immunoassay method patent, which shows that applicants screened nine of 143 cell lines developed for production of antibody necessary to practice invention, stored remainder of said cell lines, and found that four out of nine cell lines screened produced antibody falling within limitation of claims, were erroneously interpreted by Board of Patent Appeals and Interferences as failing to meet disclosure requirements of 35 USC 112, since board's characterization of stored cell lines as "failures" demonstrating unreliability of applicants' methods was improper in view of fact that such unscreened cell lines prove nothing concerning probability of success of person skilled in art attempting to obtain requisite antibodies using applicants' methods.

2. Patentability/Validity -- Adequacy of disclosure (§ 115.12)

Disclosure in application for immunoassay method patent does not fail to meet enablement requirement of 35 USC 112 by requiring "undue experimentation," even though production of monoclonal antibodies necessary to practice invention first requires production and screening of numerous antibody producing cells or "hybridomas," since practitioners of art are prepared to screen negative hybridomas in order to find those that produce desired antibodies, since in monoclonal antibody art one "experiment" is not simply screening of one hybridoma but rather is entire attempt to make desired antibody, and since record indicates that amount of effort needed to obtain desired

antibodies is not excessive, in view of applicants' success in each attempt to produce antibody that satisfied all claim limitations.

Case History and Disposition:

Appeal from decision of Patent and Trademark Office, Board of Patent Appeals and Interferences.

Application for patent of Jack R. Wands, Vincent R. Zurawski, Jr., and Hubert J. P. Schoemaker, serial number 188,735. From decision of Board of Patent Appeals and Interferences affirming rejection of application, applicants appeal. Reversed; Newman, J., concurring in part and dissenting in part in separate opinion.

Attorneys:

Jorge A. Goldstein, of Saidman, Sterne, Kessler & Goldstein (Henry N. Wixon, with them on brief), Washington, D.C., for appellant.

John H. Raubitschek, associate solicitor (Joseph F. Nakamura and Fred E. McKelvey, with him on brief), PTO, for appellee.

Judge:

Before Smith, Newman, and Bissell, circuit judges.

Opinion Text

Opinion By:

Smith, J.

This appeal is from the decision of the Patent and Trademark Office (PTO) Board of Patent Appeals and Interferences (board) affirming the rejection of all remaining claims in appellant's application for a patent, serial No. 188,735, entitled "Immunoassay Utilizing Monoclonal High Affinity IgM

Antibodies," which was filed September 19, 1980. 1 The rejection under 35 U.S.C. §112, first paragraph, is based on the grounds that appellant's written specification would not enable a person skilled in the art to make the monoclonal antibodies that are needed to practice the claimed invention without undue experimentation. We

reverse.

I. *Issue*

The only issue on appeal is whether the board erred, as a matter of law, by sustaining the examiner's rejection for lack of enablement under 35 U.S.C. §112, first paragraph, of all remaining claims in appellants' patent application, serial No. 188,735.

II. *Background*

A. *The Art.*

The claimed invention involves immunoassay methods for the detection of hepatitis B surface antigen by using high-affinity monoclonal antibodies of the IgM isotype. *Antibodies* are a class of proteins (immunoglobulins) that help defend the body against invaders such as viruses and bacteria. An antibody has the potential to bind tightly to another molecule, which molecule is called an antigen. The body has the ability to make millions of different antibodies that bind to different antigens. However, it is only after exposure of an antigen that a complicated *immune response* leads to the production of antibodies against that antigen. For example, on the surface of hepatitis B virus particles there is a large protein called *hepatitis B surface antigen* (HBsAg). As its name implies, it is capable of serving as an antigen. During a hepatitis B infection (or when purified HBsAg is injected experimentally), the body begins to make antibodies that bind tightly and specifically to HBsAg. Such antibodies can be used as reagents for sensitive diagnostic tests (*e.g* ., to detect hepatitis B virus in blood and other tissues, a purpose of the claimed invention). A method for detecting or measuring antigens by using antibodies as reagents is called an *immunoassay* .

Normally, many different antibodies are produced against each antigen. One reason for this diversity is that different antibodies are produced that bind to different regions (determinants) of a large antigen molecule such as HBsAg. In addition, different antibodies may be produced that bind to the same determinant. These usually differ in the tightness with which they bind to the determinant. *Affinity* is a quantitative measure of the strength of antibody-antigen binding. Usually an antibody with a higher affinity for an antigen will be more useful for immunological diagnostic tests than one with a lower affinity. Another source of heterogeneity is that there are several immunoglobulin classes or *isotypes* . Immunoglobulin G (IgG) is the most common isotype in serum. Another isotype, immunoglobulin M (IgM), is prominent early in the immune response. IgM molecules are larger than IgG molecules, and have 10 antigen-binding sites instead of the 2 that are present in IgG. Most immunoassay methods use IgG, but the claimed invention uses only IgM antibodies.

For commercial applications there are many disadvantages to using antibodies from serum. Serum contains a complex mixture of antibodies against the antigen of interest within a much larger pool of antibodies directed at other antigens. There are available only in a limited supply that ends when the donor dies. The goal of monoclonal antibody technology is to produce an unlimited supply of a single purified antibody.

The blood cells that make antibodies are *lymphocytes* . Each lymphocyte makes only one kind of antibody. During an immune response, lymphocytes exposed to their particular antigen divide and mature. Each produces a *clone* of identical daughter cells, all of which secrete the same antibody. Clones of lymphocytes, all derived from a single lymphocyte, could provide a source of a single homogeneous antibody. However, lymphocytes do not survive for long outside of the body in cell culture.

Hybridoma technology provides a way to obtain large numbers of cells that all produce the same antibody. This method takes advantage of the properties of *myeloma* cells derived from a tumor of the immune system. The cancerous myeloma cells can divide indefinitely in vitro. They also have the potential ability to secrete antibodies. By appropriate experimental manipulations, a myeloma cell can be made to fuse with a lymphocyte to produce a single hybrid cell (hence, a hybridoma) that contains the genetic material of both cells. The hybridoma secretes the same antibody that was made by its parent lymphocyte, but acquires the capability of the myeloma cell to divide

and grow indefinitely in cell culture. Antibodies produced by a clone of hybridoma cells (i.e., by hybridoma

cells that are all progeny of a single cell) are called monoclonal antibodies. 2

B. *The Claimed Invention .*

The claimed invention involves methods for the immunoassay of HBsAg by using high-affinity monoclonal IgM antibodies. Jack R. Wands and Vincent R. Zurawski, Jr., two of the three coinventors of the present application, disclosed methods for producing monoclonal antibodies against HBsAg in United States patent No. 4,271,145 (the '145 patent), entitled "Process for Producing Antibodies to Hepatitis Virus and Cell Lines Therefor," which patent issued on June 2, 1981. The '145 patent is incorporated by reference into the application on appeal. The specification of the '145 patent teaches a procedure for immunizing mice against HBsAg, and the use of lymphocytes from these mice to produce hybridomas that secrete monoclonal antibodies specific for HBsAg. The '145 patent discloses that this procedure yields both IgG and IgM antibodies with high-affinity binding to HBsAg. For the stated purpose of complying with the best mode requirement of 35 U.S.C. §112, first paragraph, a hybridoma cell line that secretes IgM antibodies against HBsAg (the 1F8 cell line) was deposited at the American Type Culture Collection, a recognized cell depository, and became available to the public when the '145 patent issued.

The application on appeal claims methods for immunoassay of HBsAg using monoclonal antibodies such as those described in the '145 patent. Most immunoassay methods have used monoclonal antibodies of the IgG isotype. IgM antibodies were disfavored in the prior art because of their sensitivity to reducing agents and their tendency to self-aggregate and precipitate. Appellants found that their monoclonal IgM antibodies could be used for immunoassay of HbsAg with unexpectedly high sensitivity and specificity. Claims 1, 3, 7, 8, 14, and 15 are drawn to methods for the immunoassay of HBsAg using high-affinity IgM monoclonal antibodies. Claims 19 and 25-27 are for chemically modified (*e.g* ., radioactively labeled) monoclonal IgM antibodies used in the assays. The broadest method claim reads:

1. An immunoassay method utilizing an antibody to assay for a substance comprising hepatitis B-surface antigen (HBsAg) determinants which comprises the steps of:

contacting a test sample containing said substance comprising HBsAg determinants with said antibody; and determining the presence of said substance in said sample;

wherein said antibody is a monoclonal high affinity IgM antibody having a binding affinity constant for said HBsAg determinants of at least $10^{9}M^{-1}$.

Certain claims were rejected under 35 U.S.C. §103; these rejections have not been appealed. Remaining claims 1, 3, 7, 8, 14, 15, 19, and 25-27 were rejected under 35 U.S.C. §112, first paragraph, on the grounds that the disclosure would not enable a person skilled in the art to make and use the invention without undue experimentation. The rejection is directed solely to whether the specification enables one skilled in the art to make the monoclonal antibodies that are needed to practice the invention. The position of the PTO is that data presented by Wands show that the production of high-affinity IgM anti-HBsAg antibodies is unpredictable and unreliable, so that it would require undue experimentation for one skilled in the art to make the antibodies.

III. *Analysis*

A. *Enablement by Deposit of Micro-organisms and Cell Lines .*

The first paragraph of 35 U.S.C. §112 requires that the specification of a patent must enable a person skilled in the art to make and use the claimed invention. "Patents * * * are written to enable those skilled in the art to practice the invention." 3 A patent need not disclose what is well known in the art. 4 Although we review underlying facts

found by the board under a "clearly erroneous" standard, 5 we review enablement as a question of law. 6
Where an invention depends on the use of living materials such as microorganisms or

cultured cells, it may be impossible to enable the public to make the invention (i.e., to obtain these living materials) solely by means of a written disclosure. One means that has been developed for complying with the enablement requirement is to deposit the living materials in cell depositories which will distribute samples to the public who wish to practice the invention after the patent issues. 7 Administrative guidelines and judicial decisions have clarified the conditions under which a deposit of organisms can satisfy the requirements of section 112. 8 A deposit has been held necessary for enablement where the starting materials (i.e., the living cells used to practice the invention, or cells from which the required cells can be produced) are not readily available to the public. 9 Even when starting materials are available, a deposit has been necessary where it would require undue experimentation to make the cells of the invention from the starting materials. 10
In addition to satisfying the enablement requirement, deposit of organisms also can be used to establish the filing date of the application as the prima facie date of invention, 11 and to satisfy the requirement under 35 U.S.C. §114 that the PTO be guaranteed access to the invention during pendency of the application. 12 Although a deposit may serve these purposes, we recognized, in *In re Lundak* , 13 that these purposes, nevertheless, may be met in ways other than by making a deposit.
A deposit also may satisfy the best mode requirement of section 112, first paragraph, and it is for this reason that the 1F8 hybridoma was deposited in connection with the '145 patent and the current application. Wands does not challenge the statements by the examiner to the effect that, although the deposited 1F8 line enables the public to perform immunoassays with antibodies produced by that single hybridoma, the deposit does not enable the generic claims that are on appeal. The examiner rejected the claims on the grounds that the written disclosure was not enabling and that the deposit was inadequate. Since we hold that the written disclosure fully enables the claimed invention, we need not reach the question of the adequacy of deposits.

B. *Undue Experimentation* .

Although inventions involving microorganisms or other living cells often can be enabled by a deposit, 14 a deposit is not always necessary to satisfy the enablement requirement. 15 No deposit is necessary if the biological organisms can be obtained from readily available sources or derived from readily available starting materials through routine screening that does not require undue experimentation. 16 Whether the specification in an application involving living cells (here, hybridomas) is enabled without a deposit must be decided on the facts of the particular case. 17
Appellants contend that their written specification fully enables the practice of

their claimed invention because the monoclonal antibodies needed to perform the immunoassays can be made from readily available starting materials using methods that are well known in the monoclonal antibody art. Wands states that application of these methods to make high-affinity IgM anti-HBsAg antibodies requires only routine screening, and that does not amount to undue experimentation. There is no challenge to their contention that the starting materials (i.e., mice, HBsAg antigen, and myeloma cells) are available to the public. The PTO concedes that the methods used to prepare hybridomas and to screen them for high-affinity IgM antibodies against HBsAg were either well known in the monoclonal antibody art or adequately disclosed in the '145 patent and in the current application. This is consistent with this court's recognition with respect to another patent application that methods for obtaining and screening monoclonal antibodies were well known in 1980. 18 The sole issue is whether, in this

particular case, it would require undue experimentation to produce high-affinity IgM monoclonal antibodies. Enablement is not precluded by the necessity for some experimentation such as routine screening. 19 However, experimentation needed to practice the invention must not be undue experimentation. 20 "the key word is 'undue,' not 'experimentation.' " 21

The determination of what constitutes undue experimentation in a given case requires the application of a standard of reasonableness, having due regard for the nature of the invention and the state of the art. Ansul Co. v. Uniroyal, Inc. [448 F.2d 872, 878-79; 169 USPQ 759, 762-63 (2d Cir. 1971), *cert. denied* , 404 U.S. 1018 [172 USPQ 257] (1972)]. The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed * * * . 22

The term "undue experimentation" does not appear in the statute, but it is well established that enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. 23

Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations. The board concluded that undue experimentation would be needed to practice the invention on the basis of experimental data presented by Wands. These data are not in dispute. However, Wands and the board disagree strongly on the conclusion that should be drawn from that data.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in *Ex parte Forman* . 24 They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. 25

In order to understand whether the rejection was proper, it is necessary to discuss further the methods for making specific monoclonal antibodies. The first step for making monoclonal antibodies is to immunize an animal. The '145 patent provides a detailed description of procedures for immunizing a specific strain of mice against HBsAg. Next the spleen, an organ rich in lymphocytes, is removed and the lymphocytes are separated from the other spleen cells. The lymphocytes are mixed with myeloma cells, and the mixture is treated to cause a few of the cells to fuse with each other. Hybridoma cells that secrete the desired antibodies then must be isolated from the enormous number of other cells in the mixture. This is done through a series of screening procedures.

The first step is to separate the hybridoma cells from unfused lymphocytes and myeloma cells. The cells are cultured in a medi

um in which all the lymphocytes and myeloma cells die, and only the hybridoma cells survive. The next step is to isolate and clone hybridomas that make antibodies that bind to the antigen of interest. Single hybridoma cells are placed in separate chambers and are allowed to grow and divide. After there are enough cells in the clone to produce sufficient quantities of antibody to analyze, the antibody is assayed to determine whether it binds to the antigen. Generally, antibodies from many clones do not bind the antigen, and these clones are discarded. However, by screening enough clones (often hundreds at a time), hybridomas may be found that secrete antibodies against the antigen of interest.

Wands used a commercially available radioimmunoassay kit to screen clones for cells that produce antibodies directed against HBsAg. In this assay the amount of radioactivity bound gives some indication of the strength of the antibody-antigen binding, but does not yield a numerical affinity constant, which must be measured using the more laborious Scatchard analysis. In order to determine which anti-HBsAg antibodies satisfy all of the limitations of appellants' claims, the antibodies require further screening to select those which have an IgM isotype and have a binding affinity constant of at least $10^{9}M^{-1}$. 26 The PTO does not question that the screening techniques used by Wands were well known in the monoclonal antibody art.

During prosecution Wands submitted a declaration under 37 C.F.R §1.132 providing information about all of the hybridomas that appellants had produced before filing the patent application. The first four fusions were unsuccessful and produced no hybridomas. The next six fusion experiments all produced hybridomas that made antibodies specific for HBsAg. Antibodies that bound at least 10,000 cpm in the commercial radioimmunoassay were classified as "high binders." Using this criterion, 143 high-binding hybridomas were obtained. In the declaration, Wands stated that 27

It is generally accepted in the art that, among those antibodies which are binders with 50,000 cpm or higher, there is a very high likelihood that high affinity (Ka [greater than] $10^{9}M^{-1}$) antibodies will be found. However, high affinity antibodies can also be found among high binders of between 10,000 and 50,000, as is clearly demonstrated in the Table.

The PTO has not challenged this statement.

The declaration stated that a few of the high-binding monoclonal antibodies from two fusions were chosen for further screening. The remainder of the antibodies and the hybridomas that produced them were saved by freezing. Only nine antibodies were subjected to further analysis. Four (three from one fusion and one from another fusion) fell within the claims, that is, were IgM antibodies and had a binding affinity constant of at least $10^{9}M^{-1}$. Of the remaining five antibodies, three were found to be IgG, while the other two were IgM for which the affinity constants were not measured (although both showed binding well above 50,000 cpm).

Apparently none of the frozen cell lines received any further analysis. The declaration explains that after useful high-affinity IgM monoclonal antibodies to HBsAg had been found, it was considered unnecessary to return to the stored antibodies to screen for more IgMs. Wands says that the existence of the stored hybridomas was disclosed to the PTO to comply with the requirement under 37 C.F.R. §1.56 that applicants fully disclose all of their relevant data, and not just favorable results. 28 How these stored hybridomas are viewed is central to the positions of the parties.

The position of the board emphasizes the fact that since the stored cell lines were not completely tested, there is no proof that any of them are IgM antibodies with a binding affinity constant of at least $10^{9}M^{-1}$. Thus, only 4 out of 143 hybridomas, or 2.8 percent, were *proved* to fall within the claims. Furthermore, antibodies that were proved to be high-affinity IgM came from only 2 of 10 fusion experiments. These statistics are viewed by the board as evidence that appellants' methods were not predictable or reproducible. The board concludes that Wands' low rate of demonstrated success shows that a person skilled in the art would have to

engage in undue experimentation in order to make antibodies that fall within the claims.

Wands views the data quite differently. Only nine hybridomas were actually analyzed beyond the initial screening for HBsAg binding. Of these, four produced antibodies that fell within the claims, a respectable 44 percent rate of success. (Furthermore, since the two additional IgM antibodies for which the affinity constants were never measured showed binding in excess of 50,000 cpm, it is likely that these also fall within the claims.) Wands argues that the remaining 134 unanalyzed, stored cell lines should not be written off as failures. Instead, if anything, they represent partial success. Each of the stored hybridomas had been shown to produce a high-binding antibody specific for HBsAg. Many of these antibodies showed binding above 50,000 cpm and are thus highly likely to have a binding affinity constant of at least $10^{9}M^{-1}$. Extrapolating from the nine hybridomas that were screened for isotype (and from what is well known in the monoclonal antibody art about isotype frequency), it is reasonable to assume that the stored cells include some that produce IgM. Thus, if the 134 incompletely analyzed cell lines are considered at all, they provide some support (albeit without rigorous proof) to the view that hybridomas falling within the claims are not so rare that undue experimentation would be needed to make them. The first four fusion attempts were failures, while high-binding antibodies were produced in the next six fusions.

Appellants contend that the initial failures occurred because they had not yet learned to fuse cells successfully. Once they became skilled in the art, they invariably obtained numerous hybridomas that made high-binding antibodies against HBsAg and, in each fusion where they determined isotype and binding affinity they obtained hybridomas that fell within the claims.

Wands also submitted a second declaration under 37 C.F.R. §1.132 stating that after the patent application was submitted they performed an eleventh fusion experiment and obtained another hybridoma that made a high-affinity IgM anti-HBsAg antibody. No information was provided about the number of clones screened in that experiment. The board determined that, because there was no indication as to the number of hybridomas screened, this declaration had very little value. While we agree that it would have been preferable if Wands had included this information, the declaration does show that when appellants repeated their procedures they again obtained a hybridoma that produced an antibody that fit all of the limitations of their claims.

[1] We conclude that the board's interpretation of the data is erroneous. It is strained and unduly harsh to classify the stored cell lines (each of which was proved to make high-binding antibodies against HBsAg) as failures demonstrating that Wands' methods are unpredictable or unreliable. 29 At worst, they prove nothing at all about the probability of success, and merely show that appellants were prudent in not discarding cells that might someday prove useful. At best, they show that high-binding antibodies, the starting materials for IgM screening and Scatchard analysis, can be produced in large numbers. The PTO's position leads to the absurd conclusion that the more hybridomas an applicant makes and saves without testing the less predictable the applicant's results become. Furthermore, Wands' explanation that the first four attempts at cell fusion failed only because they had not yet learned to perform fusions properly is reasonable in view of the fact that the next six fusions were all successful. The record indicates that cell fusion is a technique that is well known to those of ordinary skill in the monoclonal antibody art, and there has been no claim that the fusion step should be more difficult or unreliable where the antigen is HBsAg than it would be for other antigens.

[2] When Wands' data is interpreted in a reasonable manner, analysis considering the factors enumerated in *Ex parte Forman* leads to the conclusion that undue experimentation would not be required to practice the invention. Wands' disclosure provides considerable direction and guidance on how to practice their invention and presents working examples. There was a high level of skill in the art at the time when the application was filed, and all of the methods needed to practice the invention were well known.

The nature of monoclonal antibody technology is that it involves screening hybridomas to determine which ones secrete antibody with desired characteristics. Practitioners of this art are prepared to screen negative hybridomas in order to find one that makes the desired antibody. No evidence was presented by either party on how many hybridomas would be viewed by those in the art as requiring undue experimentation to screen. However, it seems unlikely that un

due experimentation would be defined in terms of the number of hybridomas that were never screened. Furthermore, in the monoclonal antibody art it appears that an "experiment" is not simply the screening of a single hybridoma, but is rather the entire attempt to make a monoclonal antibody against a particular antigen. This process entails immunizing animals, fusing lymphocytes from the immunized animals with myeloma cells to make hybridomas, cloning the hybridomas, and screening the antibodies produced by the hybridomas for the desired characteristics. Wands carried out this entire procedure three times, and was successful each time in making at least one antibody that satisfied all of the claim limitations. Reasonably interpreted, Wands' record indicates that, in the production of high-affinity IgM antibodies against HBsAG, the amount of effort needed to obtain such antibodies is not excessive. Wands' evidence thus effectively rebuts the examiner's challenge to the enablement of their disclosure. 30

IV. Conclusion

Considering all of the factors, we conclude that it would not require undue experimentation to obtain antibodies needed to practice the claimed invention. Accordingly, the rejection of Wands' claims for lack of enablement under 35 U.S.C. §112, first paragraph, is reversed.

REVERSED

Footnotes

Footnote 1. *In re Wands* , Appeal No. 673-76 (Bd. Pat. App. & Int. Dec. 30, 1986).
Footnote 2. For a concise description of monoclonal antibodies and their use in immunoassay see *Hybritech, Inc. v. Monoclonal Antibodies, Inc* ., 802 F.2d 1367, 1368-71, 231 USPQ 81, 82-83 (Fed. Cir. 1986), *cert. denied* , 107 S.Ct. 1606 (1987).
Footnote 3. *W.L. Gore & Assocs., Inc. v. Garlock, Inc* ., 721 F.2d 1540, 1556, 220 USPQ 303, 315 (Fed. Cir. 1983), *cert. denied* , 469 U.S. 851 (1984).
Footnote 4. *Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co* ., 730 F.2d 1452, 1463, 221 USPQ 481, 489 (Fed. Cir. 1984).
Footnote 5. *Coleman v. Dines* , 754 F.2d 353, 356, 224 USPQ 857, 859 (Fed. Cir. 1985).
Footnote 6. *Moleculon Research Corp. v. CBS, Inc* ., 793 F.2d 1261, 1268, 229 USPQ 805, 810 (Fed. Cir. 1986), *cert. denied* , 107 S.Ct. 875 (1987); *Raytheon Co. v. Roper Corp* ., 724 F.2d 951, 960 n.6, 220 USPQ 592 , 599 n.6 (Fed. Cir. 1983), *cert. denied* , 469 U.S. 835 [225 USPQ 232] (1984).
Footnote 7. *In re Argoudelis* , 434 F.2d 1390, 1392-93, 168 USPQ 99, 101-02 (CCPA 1970).
Footnote 8. *In re Lundak* , 773 F.2d 1216, 227 USPQ 90 (Fed. Cir. 1985); *Feldman v. Aunstrup* , 517 F.2d 1351, 186 USPQ 108 (CCPA 1975), *cert. denied* , 424 U.S. 912 [188 USPQ 720] (1976); Manual of Patent Examining Procedure (MPEP) 608.01 (p)(C) (5th ed. 1983, rev. 1987). *See generally* Hampar, *Patenting of Recombinant DNA Technology: The Deposit Requirement* , 67 J. Pat. Trademark Off. Soc'y 569 (1985).
Footnote 9. *In re Jackson* , 217 USPQ 804, 807-08 (Bd. App. 1982) (strains of a newly discovered species of bacteria isolated from nature); *Feldman* , 517 F.2d 1351, 186 USPQ 108 (uncommon fungus isolated from nature); *In re Argoudelis* , 434 F.2d at 1392, 168 USPQ at 102 (novel strain of antibiotic-producing microorganism isolated from nature); *In re Kropp* , 143 USPQ 148, 152 (Bd. App. 1959) (newly discovered microorganism isolated from soil).
Footnote 10. *Ex parte Forman* , 230 USPQ 546, 547 (Bd. Pat. App. & Int. 1986) (genetically engineered bacteria where the specification provided insufficient information about the amount of time and effort required); *In re Lundak* , 773 F.2d 1216, 227 USPQ 90 (unique cell line produced from another cell line by mutagenesis).
Footnote 11. *In re Lundak* , 773 F.2d at 1222, 227 USPQ at 95-96; *In re Feldman* , 517 F.2d at 1355, 186 USPQ at 113; *In re Argoudelis* , 434 F.2d at 1394-96, 168 USPQ at 103-04 (Baldwin, J. concurring).
Footnote 12. *In re Lundak* , 773 F.2d at 1222, 227 USPQ at 95-96; *In re Feldman* , 517 F.2d at 1354, 186 USPQ at 112.
Footnote 13. *In re Lundak* , 773 F.2d at 1222, 227 USPQ at 95-96.
Footnote 14. *In re Argoudelis* , 434 F.2d at 1393, 168 USPQ at 102.
Footnote 15. *Tabuchi v. Nubel* , 559 F.2d 1183, 194 USPQ 521 (CCPA 1977).
Footnote 16. *Id* . at 1186-87, 194 USPQ at 525; *Merck & Co. v. Chase Chem. Co* ., 273 F.Supp. 68, 77, 155 USPQ 139, 146 (D.N.J. 1967); *Guaranty Trust Co. v. Union Solvents Corp* ., 54 F.2d 400, 403-06, 12 USPQ 47, 50-53 (D. Del. 1931), *aff'd* , 61 F.2d 1041, 15 USPQ 237 (3d Cir. 1932), *cert. denied* , 288 U.S. 614 (1933); MPEP 608.01 (p)(C) ("No problem exists when the microorganisms used are known and readily available to the public.").
Footnote 17. *In re Jackson* , 217 USPQ at 807; *see In re Metcalfe* , 410 F.2d 1378, 1382, 161 USPQ 789, 792

(CCPA 1969).
Footnote 18. *Hybritech* , 802 F.2d at 1384, 231 USPQ at 94.
Footnote 19. *Id.; Atlas Powder Co. v. E.I. DuPont De Nemours & Co* ., 750 F.2d 1569, 1576, 224 USPQ 409, 413 (Fed. Cir. 1984); *In re Angstadt* , 537 F.2d at 502-504, 190 USPQ at 218; *In re Geerdes* , 491 F.2d 1260, 1265, 180 USPQ 789, 793 (CCPA 1974); *Mineral Separation, Ltd. v. Hyde* , 242 U.S. 261, 270-71 (1916).
Footnote 20. *Hybritech* , 802 F.2d at 1384, 231 USPQ at 94; *W.L. Gore* , 721 F.2d at 1557, 220 USPQ at 316; *In re Colianni* , 561 F.2d 220, 224, 195 USPQ 150, 153 (CCPA 1977) (Miller, J., concurring).
Footnote 21. *In re Angstadt* , 537 F.2d at 504, 190 USPQ at 219.
Footnote 22. *In re Jackson* , 217 USPQ at 807.
Footnote 23. *See Hybritech* , 802 F.2d at 1384, 231 USPQ at 94; *Atlas Powder* , 750 F.2d at 1576, 224 USPQ at 413.
Footnote 24. *Ex parte Forman* , 230 USPQ at 547.
Footnote 25. *Id.; see In re Colianni* , 561 F.2d at 224, 195 USPQ at 153 (Miller, J., concurring); *In re Rainer* , 347 F.2d 574, 577, 146 USPQ 218, 221 (CCPA 1965).
Footnote 26. The examiner, the board, and Wands all point out that, technically, the strength of antibody-HBsAg binding is measured as *avidity* , which takes into account multiple determinants on the HBsAg molecule, rather than affinity. Nevertheless, despite this correction, all parties then continued to use the term "affinity." We will use the terminology of the parties. Following the usage of the parties, we will also use the term "high-affinity" as essentially synonymous with "having a binding affinity constant of at least $10^{9}M^{-1}$."
Footnote 27. A table in the declaration presented the binding data for antibodies from every cell line. Values ranged from 13,867 to 125,204 cpm, and a substantial proportion of the antibodies showed binding greater than 50,000 cpm. In confirmation of Dr. Wand's statement, two antibodies with binding less than 25,000 cpm were found to have affinity constants greater than $10^{9}M^{-1}$.
Footnote 28. *See Rohm & Haas Co. v. Crystal Chem. Co* ., 722 F.2d 1556, 220 USPQ 98 (Fed. Cir. 1983).
Footnote 29. Even if we were to accept the PTO's 2.8% success rate, we would not be required to reach a conclusion of undue experimentation. Such a determination must be made in view of the circumstances of each case and cannot be made solely by reference to a particular numerical cutoff.
Footnote 30. *In re Strahilevitz* , 668 F.2d 1229, 1232, 212 USPQ 561, 563 (CCPA 1982).

Concurring/Dissenting Opinion Text

Concurrence/Dissent By:

Newman, J., concurring in part, dissenting in part.

A

I concur in the court's holding that additional samples of hybridoma cell lines that produce these high-affinity IgM monoclonal antibodies need not be deposited. This invention, as described by Wands, is not a selection of a few rare cells from many possible cells. To the contrary, Wands states that all monoclonally produced IgM antibodies to hepatitis B surface antigen have the desired high avidity and other favorable properties, and that all are readily preparable by now-standard techniques.
Wands states that his United States Patent No. 4,271,145 describes fully operable techniques, and is distinguished from his first four failed experiments that are referred to in the Rule 132 affidavit. Wands argues that these biotechnological mechanisms are relatively well understood and that the preparations can be routinely duplicated by those of skill in this art, as in *Hybritech, Inc. v. Monoclonal Antibodies, Inc* ., 802 F.2d 1367, 1380, 231 USPQ 81, 94 (Fed. Cir. 1986), *cert. denied* , 107 S.Ct. 1606 (1987). I agree that it is not necessary that there be a deposit of multiple exemplars of a cell system that is readily reproduced by known, specifically identified

techniques.

B

I would affirm the board's holding that Wands has not complied with 35 U.S.C. §112, first paragraph, in that he has not provided data sufficient to support the breadth of his generic claims. Wands' claims on appeal include the following:

19. Monoclonal high affinity IgM antibodies immunoreactive with HBsAg determinants, wherein said antibodies are coupled to an insoluble solid phase, and wherein the binding affinity constant of said antibodies for said HBsAg determinants is at least $10^{9}M^{-1}$.

26. Monoclonal high affinity IgM antibodies immunoreactive with hepatitis B surface antigen.

Wands states that he obtained 143 "high binding monoclonal antibodies of the right specificity" in the successful fusions; although he does not state how they were determined to be high binding or of the right specificity, for Wands also states that only nine of these 143 were tested.

Of these nine, four (three from one fusion and one from another fusion) were found to have the claimed high affinity and to be of the IgM isotype. Wands states that the other five were either of a different isotype or their affinities were not determined. (This latter statement also appears to contradict his statement that all 143 were "high binding".)

Wands argues that a "success rate of four out of nine", or 44.4%, is sufficient to support claims to the entire class. The Commissioner deems the success rate to be four out of 143, or 2.8%; to which Wands responds with statistical analysis as to how unlikely it is that Wands selected the only four out of 143 that worked. Wands did not, however, prove the right point. The question is whether Wands, by testing nine out of 143 (the Commissioner points out that the randomness of the sample was not established), and finding that four out of the nine had the desired properties, has provided sufficient experimental support for the breadth of the requested claims, in the context that "experi

ments in genetic engineering produce, at best, unpredictable results", quoting from *Ex parte Forman* , 230 USPQ 546, 547 (Bd.Pat.App. and Int. 1986).

The premise of the patent system is that an inventor, having taught the world something it didn't know, is encouraged to make the product available for public and commercial benefit, by governmental grant of the right to exclude others from practice of that which the inventor has disclosed. The boundary defining the excludable subject matter must be carefully set: it must protect the inventor, so that commercial development is encouraged; but the claims must be commensurate with the inventor's contribution. Thus the specification and claims must meet the requirements of 35 U.S.C. §112. *In re Fisher* , 427 F.2d 833, 839, 166 USPQ 18, 23-24 (CCPA 1970). As the science of biotechnology matures the need for special accommodation, such as the deposit of cell lines or microorganisms, may diminish; but there remains the body of law and practice on the need for sufficient disclosure, including experimental data when appropriate, that reasonably support the scope of the requested claims. That law relates to the sufficiency of the description of the claimed invention, and if not satisfied by deposit, must independently meet the requirements of Section 112.

Wands is not claiming a particular, specified IgM antibody. He is claiming all such monoclonal antibodies in assay for hepatitis B surface antigen, based on his teaching that such antibodies have uniformly reproducible high avidity, free of the known disadvantages of IgM antibodies such as tendency to precipitate or aggregate. It is incumbent upon Wands to provide reasonable support for the proposed breadth of his claims. I agree with the Commissioner that four exemplars shown to have the desired properties, out of the 143, do not provide adequate support.

Wands argues that the law should not be "harsher" where routine experiments take a long time. However, what

Wands is requesting is that the law be less harsh. As illustrated in extensive precedent on the question of how much experimentation is "undue", each case must be determined on its own facts. *See* , *e.g., W.L. Gore & Assocs., Inc. v. Garlock, Inc* ., 721 F.2d 1540, 1557, 220 USPQ 303, 316 (Fed. Cir. 1983), *cert. denied* , 469 U.S. 851 (1984); *In re Angstadt* , 537 F.2d 498, 504, 190 USPQ 214, 218 (CCPA 1976); *In re Cook* , 439 F.2d 730, 734-35, 169 USPQ 298, 302-03 (CCPA 1971).

The various criteria to be considered in determining whether undue experimentation is required are discussed in, for example, *Fields v. Conover* , 443 F.2d 1386, 170 USPQ 276 (CCPA 1971); *In re Rainer* , 347 F.2d 574, 146 USPQ 218 (CCPA 1965); *Ex parte Forman* , 230 USPQ at 547. Wands must provide sufficient data or authority to show that his results are reasonably predictable within the scope of the claimed generic invention, based on experiment and/or scientific theory. In my view he has not met this burden.

- End of Case -

Intellectual Property Library ISSN 1526-8535

FULL TEXT OF CASES (USPQ2D)
All Other Cases

Verdegaal Brothers Inc. v. Union Oil Company of California (CA FC)

2 USPQ2d 1051 Verdegaal Brothers Inc. v. Union Oil Company of California

U.S. Court of Appeals Federal Circuit
2 USPQ2d 1051

Decided March 12, 1987
No. 86-1258

Headnotes

PATENTS

1. Patentability/Validity -- Anticipation -- Prior art (§ 115.0703)

Federal district court erred in denying patent infringement defendant's motion for judgment n.o.v., in view of evidence demonstrating that claims for making urea-sulfuric acid fertilizer, including claims that reaction be conducted in "heat sink" of recycled fertilizer to prevent high temperature buildup, were anticipated by prior art patent that specifically detailed process for making such urea-sulfuric acid products and that explicitly taught that base or "heel" of recycled fertilizer can be used to make more of product, even if patentee of prior art did not recognize that heel functioned as heat sink, since heat sink property was inherently possessed by heel.

Particular patents -- Fertilizers

4,310,343, Verdegaal and Verdegaal, Process for Making Liquid Fertilizer, holding of validity and infringement reversed.

Case History and Disposition:

Appeal from District Court for the Eastern District of California, Coyle, J.

Action by Verdegaal Brothers Inc., William Verdegaal, and George Verdegaal, against Union Oil Company of California, and Brea Agricultural Services Inc., for patent infringement. From decision denying defendants' motion for judgment notwithstanding the verdict, defendants appeal. Reversed.

Attorneys:

Andrew J. Belansky of Christie, Parker & Hale (David A. Dillard, with him on the brief), all of Pasadena, Calif., for appelants.

John P. Sutton of Limbach, Limbach & Sutton (Michael E. Dergosits, with him on the brief), all of San Francisco, Calif., for appellees.

Judge:

Before Markey, Chief Judge, and Davis and Nies, Circuit Judges.

Opinion Text

Opinion By:

Nies, Circuit Judge.

Union Oil Company of California and Brea Agricultural Services, Inc. (collectively Union Oil) appeal from a judgment of the United States District Court for the Eastern District of California, No. CV-F-83-68 REC, entered on a jury verdict which declared U.S. Patent No. 4,310,343 ('343), owned by Verdegaal Brothers, Inc., "valid" and claims 1, 2, and 4 thereof infringed by Union Oil. Union Oil's motion for judgment notwithstanding the verdict (JNOV) was denied. We reverse.

I

BACKGROUND

The General Technology

The patent in suit relates to a process for making certain known urea-sulfuric acid liquid fertilizer products. These products are made by reacting water, urea (a nitrogen-containing chemical), and sulfuric acid (a sulfur-containing chemical) in particular proportions. The nomenclature commonly used by the fertilizer industry refers to these fertilizer products numerically according to the percentages by weight of four fertilizer constituents in the

following order: nitrogen, phosphorous, potassium, and sulfur. Thus, for example, a fertilizer containing 28% nitrogen, no phosphorous or potassium, and 9% sulfur is expressed numerically as 28-0-0-9.

The Process of the '343 Patent

The process disclosed in the '343 patent involves the chemical reaction between urea

and sulfuric acid, which is referred to as an exothermic reaction because it gives off heat. To prevent high temperature buildup, the reaction is conducted in the presence of a nonreactive, nutritive heat sink which will absorb the heat of reaction. Specifically, a previously-made batch of liquid fertilizer -- known as a "heel" -- can serve as the heat sink to which more reactants are added. Claims 1 and 2 are representative:

1. In a process for making a concentrated liquid fertilizer by reacting sulfuric acid and urea, to form an end product, the improvement comprising:

a. providing a non-reactive, nutritive heat sink, capable of dissipating the heat of urea and sulfuric acid, in an amount at least 5% of the end product,

b. adding water to the heat sink in an amount not greater than 15% of the end product,

c. adding urea to the mixture in an amount of at least 50% of the total weight of the end product,

d. adding concentrated sulfuric acid in an amount equal to at least 10% of the total weight of the end product.

2. The process of claim 1 wherein the heat sink is recycled liquid fertilizer.

Procedural History

Verdegaal brought suit against Union Oil in the United States District Court for the Eastern District of California charging that certain processes employed by Union Oil for making liquid fertilizer products infringed all claims of its '343 patent. Union Oil defended on the grounds of noninfringement and patent invalidity under 35 U.S.C. §§102, 103. The action was tried before a jury which returned a verdict consisting of answers to five questions. Pertinent here are its answers that the '343 patent was "valid" over the prior art, and that certain of Union Oil's processes infringed claims 1, 2, and 4 of the patent. None were found to infringe claims 3 or 5. Based on the jury's verdict, the district court entered judgment in favor of Verdegaal.

Having unsuccessfully moved for a directed verdict under Fed. R. Civ. P. 50(a), Union Oil timely filed a motion under Rule 50(b) for JNOV seeking a judgment that the claims of the '343 patent were invalid under sections 102 and 103. The district court denied the motion without opinion.

II

ISSUE PRESENTED

Did the district court err in denying Union Oil's motion for JNOV with respect to the validity of claims 1, 2, and 4 of the '343 patent?

III

Standard of Review

When considering a motion for JNOV a district court must: (1) consider all of the evidence; (2) in a light most favorable to the non-moving party; (3) drawing all reasonable inferences favorable to that party; (4) without determining credibility of the witnesses; and (5) without substituting its choice for that of the jury's in deciding between conflicting elements of the evidence. *Railroad Dynamics, Inc. v. A. Stucki* Co., 727 F.2d 1506, 1512-13, 220 USPQ 929, 936 (Fed. Cir.), *cert. denied* , 469 U.S. 871 [224 USPQ 520] (1984); *Connell v. Sears, Roebuck & Co* ., 722 F.2d 1542, 1546, 220 USPQ 193, 197 (Fed. Cir. 1983). A district court should grant a motion for

JNOV only when it is convinced upon the record before the jury that reasonable persons could not have reached a verdict for the nonmoving party. *Railroad Dynamics* , 727 F.2d at 1513, 220 USPQ at 936; *Connell* , 722 F.2d at 1546, 220 USPQ at 197.

To reverse the district court's denial of the motion for JNOV, Union Oil must convince us that either the jury's factual findings are not supported by substantial evidence, or, if they are, that those findings cannot support the legal conclusions which necessarily were drawn by the jury in forming its verdict. *See Perkin-Elmer Corp. v. Computervision Corp* ., 732 F.2d 888, 893, 221 USPQ 669, 673 (Fed. Cir.), *cert. denied* , 469 U.S. 857 [225 USPQ 792] (1984). *Railroad Dynamics* , 727 F.2d at 1512, 220 USPQ at 936. Substantial evidence is more than just a mere scintilla; it is such relevant evidence from the record taken as a whole as a reasonable mind might accept as adequate to support the finding under review. *Consolidated Edison Co. v. NLRB* , 305 U.S. 197, 229 (1938); *Perkin-Elmer* , 732 F.2d at 893, 221 USPQ at 673; *SSIH Equip. S.A. v. U.S. Int'l Trade Comm'n* , 718 F.2d 365, 371 n.10, 218 USPQ 678 , 684 n.10 (Fed. Cir. 1983). A trial court's denial of a motion for JNOV must stand unless the evidence is of such quality and weight that reasonable and fair-minded persons in the exercise of impartial judgment could not reasonably return the jury's verdict. *Envirotech Corp. v. Al George, Inc* ., 730 F.2d 753, 758, 221 USPQ 473, 477 (Fed. Cir. 1984).

Our precedent holds that the presumption of validity afforded a U.S. patent by 35

U.S.C. § 282 requires that the party challenging validity prove the facts establishing invalidity by clear and convincing evidence. *American Hoist & Derrick Co. v. Sowa & Sons, Inc* ., 725 F.2d 1350, 1360, 220 USPQ 763, 770 (Fed. Cir.), *cert. denied* , 469 U.S. 821 [224 USPQ 520] (1984). Thus, the precise question to be resolved in this case is whether Union Oil's evidence is so clear and convincing that reasonable jurors could only conclude that the claims in issue were invalid. *See Perkin-Elmer* , 732 F.2d at 893, 221 USPQ at 673; *Railroad Dynamics* , 727 F.2d at 1511, 220 USPQ at 935.

Anticipation

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *See, e.g., Structural Rubber Prods. Co* . v. *Park Rubber Co* ., 749 F.2d 707, 715, 223 USPQ 1264, 1270 (Fed. Cir. 1984); *Connell* , 722 F.2d at 1548, 220 USPQ at 198; *Kalman* v. *Kimberly-Clark Corp* ., 713 F.2d 760, 771, 218 USPQ 781, 789 (Fed. Cir. 1983), *cert. denied* , 465 U.S. 1026 [224 USPQ 520] (1984). Union Oil asserts that the subject claims of the '343 patent are anticipated under 35 U.S.C. § 102(e) 1 by the teachings found in the original application for U.S. Patent No. 4,315,783 to Stoller, which the jury was instructed was prior art.

From the jury's verdict of patent validity, we must presume that the jury concluded that Union Oil failed to prove by clear and convincing evidence that claims 1, 2, and 4 were anticipated by the Stoller patent. *See Perkin-Elmer* , 732 F.2d at 893, 221 USPQ at 673; *Railroad Dynamics* , 727 F.2d at 1516, 220 USPQ at 939. Under the instructions of this case, this conclusion could have been reached only if the jury found that the Stoller patent did not disclose each and every element of the claimed inventions. Having reviewed the evidence, we conclude that substantial evidence does not support the jury's verdict, and, therefore, Union Oil's motion for JNOV on the grounds that the claims were anticipated should have been granted.

The Stoller patent discloses processes for making both urea-phosphoric acid and urea-sulfuric acid fertilizers. Example 8 of Stoller specifically details a process for making 30-0-0-10 urea-sulfuric acid products. There is no dispute that Example 8 meets elements b, c, and d of claim 1, specifically the steps of adding water in an amount not greater than 15% of the product, urea in an amount of at least 50% of the product, and concentrated sulfuric acid in an amount of at least 10% of the product. Verdegaal disputes that Stoller teaches element a, the step of claim 1 of "providing a non-reactive, nutritive heat sink." As set forth in claim 2, the heat sink is recycled

fertilizer. 2
The Stoller specification, beginning at column 7, line 30, discloses:
Once a batch of liquid product has been made, it can be used as a base for further manufacture. This is done by placing the liquid in a stirred vessel of appropriate size, adding urea in sufficient quantity to double the size of the finished batch, adding any water required for the formulation, and slowly adding the sulfuric acid while stirring. Leaving a heel of liquid in the vessel permits further manufacture to be conducted in a stirred fluid mass.
This portion of the Stoller specification explicitly teaches that urea and sulfuric acid can be added to recycled fertilizer, i.e., a heel or base of previously-made product. Dr. Young, Union Oil's expert, so testified. Verdegaal presented no evidence to the contrary.
Verdegaal first argues that Stoller does not anticipate because in Stoller's method sulfuric acid is added *slowly*, whereas the claimed process allows for rapid addition. However, there is no limitation in the subject claims with respect to the rate at which sulfuric acid is added, and, therefore, it is inappropriate for Verdegaal to rely on that distinction. *See SSIH*, 718 F.2d at 378, 218 USPQ at 689. It must be assumed that slow addition would not change the claimed process in any respect including the function of the recycled material as a heat sink.
Verdegaal next argues that the testimony of Union Oil's experts with respect to what

Stoller teaches could well have been discounted by the jury for bias. Discarding that testimony does not eliminate the reference itself as evidence or its uncontradicted disclosure that a base of recycled fertilizer in a process may be used to make more of the product.
[1] Verdegaal raises several variations of an argument, all of which focus on the failure of Stoller to explicitly identify the heel in his process as a "heat sink." In essence, Verdegaal maintains that because Stoller did not recognize the "inventive concept" that the heel functioned as a heat sink, Stoller's process cannot anticipate. This argument is wrong as a matter of fact and law. Verdegaal's own expert, Dr. Bahme, admitted that Stoller discussed the problem of high temperature caused by the exothermic reaction, and that the heel could function as a heat sink. 3 In any event, Union Oil's burden of proof was limited to establishing that Stoller disclosed the same process. It did not have the additional burden of proving that Stoller recognized the heat sink capabilities of using a heel. Even assuming Stoller did not recognize that the heel of his process functioned as a heat sink, that property was inherently possessed by the heel in his disclosed process, and, thus, his process anticipates the claimed invention. *See In re Oelrich*, 666 F.2d 578, 581, 212 USPQ 323, 326 (CCPA 1981); *In re Swinehart*, 439 F.2d 210, 212-13, 169 USPQ 226, 229 (CCPA 1971). The pertinent issues are whether Stoller discloses the process of adding urea and sulfuric acid to a previously-made batch of product, and whether that base would in fact act as a heat sink. On the entirety of the record, these issues could only be resolved in the affirmative.
On appeal Verdegaal improperly attempts to attack the status of the Stoller patent as prior art, stating in its brief: Verdegaal also introduced evidence at trial that the Stoller patent is not prior art under 35 U.S.C. §§ 102(e)/103. Professor Chisum testified that the Stoller patent, in his opinion, was not prior art. . . . This conclusion finds support in *In re Wertheim*, 646 F.2d 527 [209 USPQ 554] (CCPA 1981), and 1 Chisum on Patents §3.07[3]. Appellee Brief at 27 (record cite omitted). Seldom have we encountered such blatant distortion of the record. A question about the status of the Stoller disclosure as prior art did arise at trial. Union Oil asserted that, even though the Stoller patent issued after the '343 patent, Stoller was prior art under section 102(e) as of its filing date which was well before the filing date of Verdegaal's application. Professor Chisum never testified that the Stoller patent was *not* prior art, but rather, stated that *he did not know* whether it was prior art. An excerpt from the pertinent testimony leaves no doubt on this point:
Q. (Mr. Sutton): And do you know whether the Stoller patent is prior art to the application of the Verdegaal patent?
A. (Prof. Chisum): I don't know that it is, no.
We find it even more incredible that Verdegaal would attempt to raise an issue with respect to the status of the

Stoller patent given that the case was submitted to the jury with the instruction that the original Stoller patent application was prior art. 4 Verdegaal made no objection to that instruction below, and in its appeal briefs, the instruction is cavalierly ignored.

In sum, Verdegaal is precluded from arguing that the Stoller patent should not be considered prior art. *See* Fed. R. Civ. P. 51; *Weinar v. Rollform Inc* ., 744 F.2d 797, 808, 223 USPQ 369, 375 (Fed. Cir. 1984), *cert. denied* , 105 S.Ct. 1844 (1985); *Bio-Rad Laboratories, Inc. v. Nicolet Instrument Corp* ., 739 F.2d 604, 615, 222 USPQ 654, 662 (Fed. Cir.), *cert. denied* , 469 U.S. 1038 (1984). 5

After considering the record taken as a whole, we are convinced that Union Oil established anticipation of claims 1, 2, and 4 by clear and convincing evidence and that no reasonable juror could find otherwise. Consequently, the jury's verdict on validity is unsupported by substantial evidence and

cannot stand. Thus, the district court's denial of Union Oil's motion for JNOV must be reversed.

Conclusion

Because the issues discussed above are dispositive of this case, we do not find it necessary to reach the other issues raised by Union Oil. 6 In accordance with this opinion, we reverse the portion of the judgment entered on the jury verdict upholding claims 1, 2, and 4 of the '343 patent as valid under section 102(e) and infringed.

REVERSED

Footnotes

Footnote 1. Section 102(e) provides:

A person shall be entitled to a patent unless--

. . . .

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent

. . . .

Footnote 2. Claim 4 is written in terms of approximate percentages of all reactants by weight of the end product. No argument is made that the process of claim 4 would result in a fertilizer product any different from that disclosed by Example 8 of Stoller.

Footnote 3. There is no dispute that the percentage of heel described in Stoller meets the percentage of heat sink required by the claims.

Footnote 4. The jury instruction read:

Stoller filed two patent applications -- an original application on October 30th, 1978, and a second on February 7th, 1980. Under the patent laws, the claims of the 343 patent are invalid if you find that the original application (Exhibit BL) anticipates the process claimed in the 343 patent.

Footnote 5. Union Oil also argues that Verdegaal's counsel misled the jury by its closing rebuttal argument:

ut I think it's important to keep in mind that [Stoller] couldn't have been a prior patent because it issued a month after the Verdegaal patent had issued.

We disapprove of Verdegaal's tactic which would form the basis for a grant of a motion for a new trial but for our conclusion that outright reversal of the ruling on the motion for JNOV is in order.

Footnote 6. It should not be inferred that all of these issues were properly before us. Union Oil appears to assume that on appeal it may dispute the resolution of any *issue* which is denominated an "issue of law" even though it was not raised in its motion for JNOV. This is incorrect. *See Railroad Dynamics* , 727 F.2d at 1511, 220 USPQ at 934.

- End of Case -

Intellectual Property Library ISSN 1526-8535

In re ROYKA AND MARTIN

(CCPA)
180 USPQ 580
Decided Feb. 7, 1974
No. 9092
U.S. Court of Customs and Patent Appeals

Headnotes

PATENTS

1. Patentability — Anticipation — Combining references (§ 51.205)
To support anticipation rejection, all elements of claim must be found in reference.

2. Construction of specification and claims — Broad or narrow — In general (§ 22.101)

Construction of specification and claims — By specification and drawings — In general (§ 22.251)
Claims are not read in a vacuum; while they are given broadest reasonable interpretation during prosecution, their terms still must be given meaning called for by specification of which they form a part.

3. Patentability — Anticipation — In general (§ 51.201)
Anticipation requires a finding that claimed invention be disclosed; it is not enough to say that applicants' invention and the reference are both usable for instruction and both consist of permanent and removable printings on paper.

4. Patentability — Subject matter for patent monopoly — Printed matter (§ 51.611)
It is not a valid reason for rejection that claim is merely a printed matter variation of design of reference; printed matter may very well constitute structural limitations upon which patentability can be predicated.

Particular patents—Answer System
Royka and Martin, Responsive Answer System, claims 28 and 30 to 36 of application allowed.

Case History and Disposition:

Appeal from Board of Appeals of the Patent Office.

Application for patent of Stephen F. Royka and Robert G. Martin, Serial No. 648,701, filed June 26, 1967; Patent Office Group 336. From decision rejecting claims 28 and 30 to 36, applicants appeal. Reversed.

Attorneys:

MICHAEL H. SHANAHAN, Fairport, N. Y. (THOMAS M. WEBSTER, Fairport, N. Y., and BORIS HASKELL and PARIS, HASKELL & LEVINE, both of Arlington, Va., of counsel) for appellants.

JOSEPH F. NAKAMURA (FRED W. SHERLING of counsel) for Commissioner of Patents.

Judge:

Before MARKEY, Chief Judge, and RICH, BALDWIN, LANE, and MILLER, Associate Judges.

Opinion Text

Opinion By:

RICH, Judge.

This appeal is from the decision of the Patent Office Board of Appeals affirming the examiner's rejection of claims 28 and 30-36 of application serial No. 648,701, filed June 26, 1967, entitled "Responsive Answer System." We reverse.

The Invention

The appealed claims are directed to a device in the nature of an answer sheet for use in self-instruction and testing. The answer sheet may be associated with questions or separate therefrom. The essential features of the invention are that there are printed on the answer sheet in "response areas" meaningful information in permanent printing and confusing information in printing which can be removed, as by an eraser, both being legible so that a student, seeing a choice of answers to a question, must make a selection. Having made a selection, he then applies an eraser to the selected response area and some of the information will be readily removed. What remains advises him of the correctness or otherwise of his answer. The following figures from the drawings are illustrative:
Tabular, graphic, or textual material set at this point is not available. Please consult hard copy or call BNA PLUS at 1-800-452-7773 or 202-452-4323.

Tabular, graphic, or textual material set at this point is not available. Please consult hard copy or call BNA PLUS at 1-800-452-7773 or 202-452-4323.

Fig. 1A shows two response areas to a given question before any removing action by the student has taken place

and Fig. 1B shows the permanent information remaining in each after erasure of the removable information. Of course, if the student makes an initial choice of area A, showing up "YES" or some other indication of a correct answer, he will not need to proceed further and erase the B area. In a modified form of the invention, a wrong selection, plus erasure, may expose, instead of or in addition to a statement that the answer is wrong, a number or other reference to further material which is to be studied.

A preferred method of printing the permanent meaningful information and the removable confusing information is by that type of xerography in which a fusible toner is used, the permanence of the printing depending on the extent to which the toner image is "fixed" or fused by heat. By successive printings of the two kinds of information with fixing to different degrees, one image can be made permanent and the other made subject to easy removal, both images retaining such similarity of appearance that the user of the answer sheet cannot tell them apart.

Claim 28 is the principal claim, all others being dependent thereon, and reads as follows:

> 28. A device for selectively indicating information comprising
>
> a support having response areas for presenting information for selection,
>
> permanent printing indicative of meaningful information permanently fixed to said support within a response area, and
>
> removable printing indicative of confusing information removably fixed to said support within a response area,
>
> said meaningful and confusing information being substantially legible even when said permanent and removable printing are fixed over one another on said support,
>
> said permanent and removable printing being substantially similar such that an observer cannot determine which information is permanent and which is removable
>
> whereby the information within a response area is selected by attempting to remove the printing therein with the failure to remove printing identifying meaningful information.

Claims 30-36 add limitations which need not be considered except for noting that claims 33 and 34 alone specify the use of a xerographic toner, for which reason they were rejected on a different ground from the other claims.

The Rejection

The following references were relied on:

> Reid et al. (Reid) 356,695 Jan. 25, 1887
>
> Bernstein et al. (Bernstein) 3,055,117 Sep. 25, 1962
>
> Lein et al. (Lein) 3,364,857 Jan. 23, 1968 (filed Feb. 2, 1966)

Claims 28, 30, 31, and 32 were rejected as anticipated under 35 U.S.C. 102 by Bernstein; claims 28, 31, 32, 35, and 36 were rejected as anticipated under § 102 by Reid; and claims 33 and 34 were rejected under 35 U.S.C. 103 for obviousness, on either Bernstein or Reid in view of Lein. These were the examiner's rejections and the board affirmed them, adhering to its decision on reconsideration.

Bernstein discloses an answer sheet in which printed information representing a response is "temporarily concealed from the observer" and he discloses a number of different ways of effectively concealing the response. His specification states:

> The objects of the invention are accomplished by utilizing the hiding media to confuse the participant and to render the response and the hiding media indistinguishable and thus conceal the presence, absence, nature or position of the response from the participant. This may be effectuated by careful attention being paid to a number of factors including the design, color and position of the hiding or confusing media.

Fig. 1 of Bernstein's drawings illustrates some of his concealing means:

Tabular, graphic, or textual material set at this point is not available. Please consult hard copy or call BNA PLUS at 1-800-452-7773 or 202-452-4323.

The following is the written description:

> Referring now to the drawing, FIG. 1 illustrates some of the many optically confusing patterns which may be positioned between the printed structure to be concealed and the point of observation. Column 11 shows the information which is to be concealed. This information is repeated in columns 12 through 16 but in each case is concealed by a pattern in accordance with the present invention. Column 12 utilizes a pattern comprising an alphabetical maze in both line and half tone screen. Column 13 utilizes a pattern comprising an absorbing field having a plurality of irregular dot-like interstices. Column 14 utilizes a pattern comprising a maze of plus signs combined with dots. Columns 15 and 16 illustrate irregular and non-repetitious patterns.

Bernstein says that if at least 50% of the response is actually covered by the opaque portions of the confusion pattern, complete concealment is obtained. He also says that added means of concealment may be used, such as scoring and embossing and perforating the paper in order to scatter the light or let it shine through.

Reid is entitled "Transformation Picture and Print." The invention is said to be useful for advertisements, Christmas cards, birthday cards, valentines, and the like and as a source of amusement and instruction for children. It consists of a picture or print, part of which is permanently printed and part of which is removable from the paper on which it is printed. For the latter various soluble undercoatings or inks are described. If the picture is washed with a solvent, which may be water, the removable part disappears and the pictorial and/or typographic matter changes. The invention is illustrated by a typical nineteenth century temperance propaganda piece depicting the evils of drink. In the finished picture there are three scenes from left to right: Scene 1, the innocent child leads her father home from the pub; Scene 2, Father sits slumped in the kitchen chair with his bottle beside him, the family wash hanging above his head, this picture being entitled "The Effects of Drink"; Scene 3, Mother stands in front of a sign reading "Pawn Shop." Across the bottom of the picture is a legend which says "Wash the above and see what water will do." Fig. II shows the result of washing with water: Scene 1, a handsome young man and his happy daughter stroll on the street; Scene 2, Father sits erect in a well-appointed room at a cloth-covered table, apparently having a cup of tea, obviously a gentleman; Scene 3, Mother beams from the sideline and the Pawn Shop sign has vanished. Two new subscriptions appear and the words "The" and "Drink" have disappeared, the resultant being a new picture title reading "The Beneficial Effects of Temperance." "The Beneficial" and "Temperance" were covered by some soluble opaque in the original picture. No doubt the overall effect is instruction. Perhaps there was amusement in bringing about the transformation.

Lein relates to xerography and is relied on only for its disclosure of the removability of partially fused toner and the permanence of fully fused toner.

Opinion

[1] As to the § 102 anticipation rejections, it will suffice to consider independent claim 28. If it is not fully met by Reid or Bernstein, neither are the more limited dependent claims. It is elementary that to support an anticipation rejection, all elements of the claim must be found in the reference. We do not find claim 28 anticipated by Bernstein because, as we read the claim, it requires the display of *legible* meaningful and *legible* confusing *information* simultaneously, between which the user of the device may make a selection before he undertakes to remove any of the information from the response area selected by him. The element we find most clearly missing, contrary to the reasoning of the examiner and the board, is the legible confusing *information.* The Patent Office proposes to read this limitation on Bernstein's confusion patterns which are nothing but meaningless obscuring screens, conveying no information and providing the user with no basis for making a *selection* , as called for by

claim 28. In appellants' device the legible confusing information—i.e., the wrong answers—are legible in the sense that they can be read as intelligible words, not merely a jumble of type serving to obscure the words of the wrong answers.

Appellants were fully aware of Bernstein and discussed its disclosures in their specification, distinguishing from this and other prior art, saying, in part:

> The inventive concept hereof confuses not by physical blocking as taught by the prior art, but by compounding, associating (including disarranging) permanent information with confusing information, usually at least some of which is similar in character to the permanent information as to render it impossible to tell which is permanent and which is removable confusing information. In the invention, generally no attempt is made to designedly physically cover the permanent information, but to confuse it beyond interpretation by the presentation of extraneous, removable, confusing information.

[2] Claims are not to be read in a vacuum and while it is true they are to be given the broadest *reasonable* interpretation during

prosecution, their terms still have to be given the meaning called for by the specification of which they form a part. We cannot read the terms "legible" and "information" on Bernstein's confusion patterns, as did the examiner and the board. They are not "legible," as appellants use the term, and they convey no information.

As to anticipation by Reid, we find neither appellants' basic concept nor the substance of claim 28 to be disclosed. Apparently the solicitor could find little to support the rejection in Reid for all he says in his brief—so far as claim 28 is concerned—is:

> Reid discloses a sheet which may be used for instruction and which may have a removable design partly covering a fixed design * * *. Therefore, the disclosure of the reference encompasses the arrangement wherein a removable design covers a fixed design with both designs being substantially legible.

[3]But claim 28 does not call for an arrangement wherein a removable design covers a fixed design. It calls for response areas, which Reid does not have, containing meaningful information in permanent printing together with removable printing conveying confusing information, both legible at the same time, between which a "selection" can be made. The only choice offered to the user by Reid is to follow the instruction to wash the whole visible picture with water or other solvent, thus removing the overprinting, to discover what the permanent picture is. The Patent Office attempt to read claim 28 on this reference is a tour de force. We hold that Reid does not anticipate for failure to meet the limitations of claim 28 to "response areas," to the presentation of two categories of information (meaningful-permanent and removable-confusing) within such areas, and the possibility of selection. Anticipation requires a finding that the claimed invention be disclosed. It is not enough to say that appellants' invention and the reference are both usable for instruction and both consist of permanent and removable printings on paper, as did the solicitor.

The dependent claims rejected with claim 28, as anticipated under § 102, are not anticipated since claim 28 is not anticipated. Some of them merely add features which are disclosed by the references and some do not. Insofar as they do not, they further negative anticipation. The examiner recognized this fact as to claims 33 and 34, which are limited to xerography, and therefore did not reject them under § 102. Similarly, he did not reject claim 30 on Reid or claims 35 and 36 on Bernstein. We find that claims 35 and 36 contain limitations which additionally distinguish from Reid. We have already noted that Reid has no "response areas" as required by claim 28 and so Reid does not disclose the structure of claim 35 which additionally requires both the correct and incorrect answers to appear within the same response area.

[4] As to claim 36, the examiner said it "is merely a printed matter variation of the design of the reference,"

Reid. This is not a valid reason for rejection. Printed matter may very well constitute structural limitations upon which patentability can be predicated. We have commented on this matter in In re Jones, 54 CCPA 1218, 373 F.2d 1007, 153 USPQ 77 (1967); and In re Miller, 57 CCPA 809, 418 F.2d 1392, 164 USPQ 46 (1969), and will not repeat ourselves. The limitations of claim 36 are not remotely suggested by Reid.

There remains the § 103 rejection of claims 33 and 34. Do they, taken together with all of the limitations of claim 28 from which they depend, define obvious subject matter? The difference between claim 28 and these two dependent claims is that they add the limitations to xerography. If Bernstein and Reid showed the claimed invention except for xerography, the addition of the Lein reference would make the subject matter of the claims obvious. But that is not the situation here. Adding the knowledge of xerographic technology to Bernstein or Reid still does not make the invention of claims 33 and 34 obvious for the same reasons we have given above in discussing anticipation. The essence of appellants' invention, as set forth in claim 28, is still missing notwithstanding the addition of the Lein reference and we see nothing in the combinations of references which would have made the invention obvious to one of ordinary skill in the art at the time it was made. We will, therefore, reverse this rejection.

The decision of the board is *reversed* .

- End of Case -

 ISSN 1526-8535

Intellectual Property Library ISSN 1526-8535

In re Wilson

(CCPA)
165 USPQ 494
Decided May 7, 1970
No. 8271
U.S. Court of Customs and Patent Appeals

Headnotes

PATENTS

1. Claims - Indefinite - In general (§ 20.551)

Construction of specification and claims - In general (§ 22.01)

All words in claim must be considered in judging patentability of claim against prior art; if no reasonably definite meaning can be ascribed to terms in claim, subject matter does not become obvious - the claim becomes indefinite.

Particular patents-Brush

Wilson, Treated Brush and Brush Treating Composition, claims 1 to 4, 8 to 10, and 15 to 21 of application allowed.

Case History and Disposition:

Appeal from Board of Appeals of the Patent Office.

Application for patent of David W. Wilson, Serial No. 332,321, filed Nov. 5, 1963; Patent Office Group 146. From decision rejecting claims 1 to 4, 8 to 10, and 15 to 21, applicant appeals. Reversed.

Attorneys:

Oberlin, Maky, Donnelly & Renner, William E. Thomson, Jr., and John C. Oberlin, all of Cleveland, Ohio, for appellant.

Joseph Schimmel (Raymond E. Martin of counsel) for Commissioner of Patents.

Judge:

Before Rich, Acting Chief Judge, Almond, Baldwin, and Lane, Associate Judges, and Ford, Judge, United States Customs Court, sitting by designation.

Opinion Text

Opinion By:

Lane, Judge.

This appeal is from the decision of the Patent Office Board of Appeals, which affirmed the rejection of claims 1-4, 8-10, and 15-21 in appellant's application serial No. 332,321, filed November 5, 1963, for "Treated Brush and Brush Treating Composition." Four other claims have been allowed. We conclude that the board's decision must be reversed.

The Disclosure

Appellant's disclosure discusses certain problems in the treatment of power-driven rotary brushes. According to the disclosure, it was desirable to produce a composition for treating the brush bristles, whereby the ability of the bristles to hold abrasive particles would be enhanced. It discloses that the treatment composition should have a strength of adhesion to the brush bristles sufficiently great to prevent such composition from transferring excessively to the object being brushed; that the treatment material should wear at substantially the same rate as the brush bristles; that the material should have a high temperature softening point; and that the strength of adhesion between the treating composition and the abrasive particles must be sufficient to withstand the centrifugal force which normally would tend to throw the abrasive outwardly from the brush. The disclosure states that previously known brush-treating compositions did not accomplish all these objectives and had a tendency to dry and lose their tackiness over a period of time, thus becoming useless for holding abrasive particles on the bristles.

The disclosure states that appellant discovered that a composition having a high temperature softening point and a high degree of tackiness could be produced if a film-forming resin were blended with a tackifier resin which was incompatible with (insoluble in) the film-forming resin. The resulting composition would have two distinct phases: a continuous phase comprised of film-forming resin, either alone or saturated with a small quantity of tackifier resin, and a dispersed phase comprised of small particles of tackifier resin. The two resins may be either completely or partially incompatible, and the disclosure states that the more insoluble the resins, the greater the tack which the composition possesses. Appellant also disclosed that certain plasticizers could be added to render the resins more incompatible, thus further increasing the tack of the composition. Finally, appellant stated that the entire composition could be dissolved in a volatile solvent to allow easy application to the brush, the solvent being one which quickly evaporates upon such application.

The specification contains a list of suitable film-forming resins, including ethyl cellulose, nitro cellulose, cellulose acetate, polyvinyl acetate and cis-polyisoprene, among other materials. A list of tackifiers is given, including certain esters of abietic acid, polyvinyl ethyl ether, coumarone indene resin and terpene resins. A list of plasticizers is also given. The specification then gives four ex

amples showing how to combine various film-formers, tackifiers, plasticizers and solvents to obtain brush-treating compositions of the desired characteristics, and explains how to apply them to brushes.

The Claims

In view of the result we reach, we find that claims 1 and 8 are representative:

> 1. A two-phase brush treating composition having a high softening point and sufficient tack to retain abrasive material firmly adhered to brush fill material comprising a film-forming resin and a tackifier resin which is incompatible with said film-forming resin, said two phases comprising a continuous phase formed of said film-forming resin and a dispersed phase formed of small particles of tackifier resin.
>
> 8. In combination, a rotary brush having brush fill material and a two-phase pressure sensitive adhesive brush treating composition adhered thereto having a high softening point and sufficient tack to retain abrasive material firmly adhered to such brush fill material comprising a film-forming resin and a tackifier resin which is incompatible with said film-forming resin, said two phases comprising a continuous phase formed of said film-forming resin and a dispersed phase formed of small particles of tackifier resin.

The remaining claims on appeal are narrower, containing recitations of specific resins, plasticizers, etc.

The Prior Art

Grantham [1] relates to coatings for film material and discloses a coating composition comprising a cellulose derivative film-former, a blending resin, a plasticizer, and an organic solvent. Grantham teaches that the blending agent and the film-former should be compatible.

Depew [2] teaches the preparation of emulsions consisting of a continuous phase of water and a discontinuous phase of elastomer particles and particles of a volatile hydrocarbon, with vulcanizing ingredients and other additives dispersed in the hydrocarbon particles. Depew then states that where a dispersion with additional adhesive properties is desired, an adhesive, such as certain of the tackifier resins disclosed by appellants, can be added to the emulsion, and that

> [t]his adhesive can be water soluble or dispersed as particles. * * * The chemistry of the adhesive component is not critical to this invention. The important thing is that the deposited film shall be tacky and adhesive.

Sergi [3] relates to adhesives suitable for installation of floor-covering products such as linoleum. Sergi's composition consists of a tackifier resin dispersed in a latex binder; the tackifier and latex must be compatible with one another, according to the Sergi disclosure.

Vaughan [4] teaches impregnating a fibrous buffing wheel with an aqueous emulsion consisting of a tacky resin and an emulsifier or stabilizer such as glue or gum.

The Board

The board found the composition claims to be unpatentable over Depew, Sergi or Grantham under 35 U.S.C. 103. The board reached this conclusion after noting that each of the three references shows some of the film-formers, tackifiers, plasticizers and solvents appearing in appellant's lists. The board found that the recited limitation of incompatibility was too relative a term to distinguish over the compositions of the references.

The board found that the claims to the treated brush were unpatentable, under 35 U.S.C. 103, over Vaughan in view of Sergi or Depew. Since Vaughan shows treating brushes, the board apparently considered it obvious to treat brushes with compositions which it thought were made obvious by Sergi or Depew.

The board also affirmed the rejection of certain claims for being "broader than the disclosure" under 35 U.S.C. 112. The board's basis for this rejection was that the specification did not provide adequate guidelines for making a selection among the various disclosed ingredients, nor among other materials which are not disclosed but would be included by the claims.

Opinion

We first treat the rejection under section 112. This rejection is in effect an attack on the specification as being

insufficient to teach how to practice the broad invention claimed. The rejection is therefore under the first paragraph of section 112. The board's position, as mentioned above, was that the specification did not teach how to select ingredients so that the desired incompatibility would result. We disagree with the board's position on this point. First of all, appellant provided four examples, each specifying the nature and amounts of materials to be used. Secondly,

the record indicates that it involves only routine experimentation to find out which resins are incompatible. The examiner admitted as much when, with regard to obviousness, he said "selecting the proper tackifier and film-forming resin from those listed in the references to form an emulsion or two-phase composition would be within the expected skill of the art and would merely involve routine experimentation." We conclude that appellant has provided a sufficient specification to support the claims here in issue.

[1] Turning to the rejection of the claims for obviousness, we again disagree with the board's position. The board has disregarded the term "incompatible," as used in the claims, because it is "too relative" to distinguish over the compositions of the references. Appellant contends this limitation is essential in defining his invention. There has been no rejection here for indefiniteness, under the second paragraph of section 112. Rather than reject the claims as indefinite, the board chose to ignore the language it considered indefinite, and proceeded as though that language were not in the claims. The board said, in effect, that since we do not know what "incompatible" means, and the rest of the claim defines obvious subject matter, there is no basis for concluding unobviousness. This reasoning is incorrect. All words in a claim must be considered in judging the patentability of that claim against the prior art. If no reasonably definite meaning can be ascribed to certain terms in the claim, the subject matter does not become obvious-the claim becomes indefinite. In the present case, we think the term "incompatible" is defined with reasonable definiteness in the specification. While it is true that the word is not perfectly precise, under the circumstances of the present case there appears to be no other way for appellant to describe his discovery. In any event, the ignoring of this term by the board renders its conclusion of obviousness unsupported. None of the references discloses a two-phase composition of incompatible resins or suggests that such a composition would have the properties disclosed by appellant. Grantham and Sergi both expressly teach that the components of their compositions should be compatible. Neither Vaughan nor Depew uses a resin as the continuous phase. While Depew states, as quoted above, that the adhesive material may be dispersed as particles in the continuous phase, and hence be incompatible with the continuous phase material, it cannot be ignored that Depew's continuous phase is of water, not a film-forming resin as recited in appellant's claims. Furthermore, there is no suggestion in Depew or Vaughan that there are advantages in using an adhesive which is insoluble in the aqueous phase. There is nothing of record, therefore, from which we can properly conclude that the subject matter of appellant's claims would have been obvious at the time of his invention. The decision of the board must accordingly be *reversed.*

Footnotes

Footnote 1. U. S. Pat. 3,051,670, issued August 28, 1962.
Footnote 2. U. S. Pat. 2,933,469, issued April 19, 1960.
Footnote 3. U. S. Pat. 3,015,638, issued January 2, 1962.
Footnote 4. U. S. Pat. 2,890,136, issued June 9, 1959.

- End of Case -

Intellectual Property Library ISSN 1526-8535

FULL TEXT OF CASES (USPQ2D)
All Other Cases

Hodosh v. Block Drug Co., Inc. (CA FC) 229 USPQ 182 Hodosh v. Block Drug Co., Inc.

U.S. Court of Appeals Federal Circuit
229 USPQ 182

Decided March 24, 1986
No. 85-2607

Headnotes

PATENTS

1. Patentability/Validity -- Obviousness -- Relevant prior art -- In general (§ 115.0903.01)

Summary judgment holding that claimed tooth desensitizer was invalid for obviousness was improper, in view of existing questions of material fact concerning various terms used in Chinese and European references.

2. Patentability/Validity -- Obviousness -- Secondary considerations generally (§ 115.0907)

Secondary considerations and additional evidence likely to be considered at trial must be considered in obviousness determination.

Particular patents -- Dental Treatments

3,863,006, Hodosh, Method for Desensitizing Teeth, holding of invalidity reversed.

Case History and Disposition:

Appeal from District Court for the District of New Jersey, Sarokin, J.; 226 USPQ 645 .

Action by Milton Hodosh, and Richardson-Vicks, Inc., against Block Drug Company, Inc., and Dentco, Inc., for patent infringement. From summary judgment for defendants, plaintiffs appeal. Reversed and remanded.

Attorneys:

John O. Tramontine, and Fish & Neave, and Hugh A. Chapin, and Kenyon & Kenyon, all of New York, N.Y. (W. Edward Bailey, Norman H. Beamer, Fish & Neave, Paul Lempel, William J. McNichol, and Kenyon & Kenyon, all of New York, N.Y., on the brief) for appellants.

Jerome G. Lee, and Morgan, Finnegan, Pine, Foley & Lee, both of New York, N.Y. (William S. Feiler, Maria C.H. Lin, Morgan, Finnegan, Pine, Foley & Lee, Marvin C. Soffen, Edward A. Meilman, and Ostrolenk, Faber, Gerb & Soffen, all of New York, N.Y., on the brief) for appellees.

Judge:

Before Rich, Davis, and Baldwin, Circuit Judges.

Opinion Text

Opinion By:

Rich, Circuit Judge.

This appeal is from the July 12, 1985, judgment of the United States District Court for the District of New Jersey, 226 USPQ 645 , granting summary judgment to Block Drug Company, Inc., et al. (Block) and holding that all six claims of patent No. 3,863,006 for "Method of Desensitizing Teeth" ('006 patent), issued to Dr. Milton Hodosh and licensed to Richardson-Vicks, Inc. (collectively, Hodosh), are invalid for obviousness under 35 USC 103. We reverse remand.

Background

Tooth desensitizers reduce discomfort and pain caused by tooth hypersensitivity or exposed dentin, the portion of the tooth between the enamel and the pulp which includes a myriad of microscopic tubules. Persons suffering from this condition react painfully to hot or cold foods, citric acid or sweets, or everyday chemical, thermal, or tactile stimuli including toothbrush contact.

Milton Hodosh, a practicing dentist for about thirty years, independently developed the claimed subject matter of

the '006 patent and granted Richardson-Vicks an exclusive license to make, use, and sell the claimed invention; the latter markets its tooth desensitizing toothpaste under the trademark "Denquel."
Claim 1 of the '006 patent 1 reads:
The method of desensitizing hypersensitive dentin and cementum by applying thereto an agent the essential ingredient of which is a nitrate of one of the following alkali metals: potassium, lithium or sodium said nitrate comprising between 1 percent and 20 percent by weight of said agent.
The remaining claims appear in the opinion below.
Appellee Block has, since 1961, marketed a tooth desensitizing toothpaste, covered by its patent No. 2,122,483 (the Rosenthal patent) for "Strontium Ion Toothpaste" issued in 1964, under the trademark "Sensodyne." The Rosenthal patent and the '006 patent disclose toothpaste formulae which are the same except that the latter contains, as a desensitizing agent, potassium nitrate instead of the Rosenthal-Block strontium chloride. After requesting and being denied a license under the '006 patent, Block developed its own potassium nitrate-containing tooth-desensitizing toothpaste called "Promise" and "Sensodyne-F." 2

March 30, 1983, Hodosh sued Block alleging that the sale of "Promise" and "Sensodyne-F" contributorily infringed and actively induced infringement of the '006 patent. Block answered and counterclaimed alleging patent misuse and consequent unenforceability of the '006 patent. On July 11, 1984, Block moved for summary judgment as to both misuse and patent invalidity. Oral argument was heard October 16, 1984, and decision was reserved. June 14, 1985, the reported decision was handed down granting the motion as to patent invalidity and dismissing the motion on misuse as moot, resulting in the judgment now on appeal.
The district court heard no expert testimony, but did hear arguments of counsel, receive briefs, review exhibits, and had before it declarations and affidavits from experts on both sides commenting on the eight prior art references involved here, including the Rosenthal patent. The court determined that there were no genuine issues of material fact and concluded as a matter of law that the claims of the '006 patent were invalid under §103 because the Rosenthal patent disclosed each element claimed in the '006 patent except the potassium nitrate, which, in its view, was disclosed in two Chinese references, both based on ancient Chinese writings. The court also stated that six European references supported its conclusion of obviousness.
Because the appropriateness of summary judgment is determined on an analysis of the facts, *First National Bank of Arizona* v. *Cities Service Co.,* 391 U.S. 253 (1968), and because everything about these references, as a whole, *see, e.g., Interconnect Planning Corp.* v. *Feil,* 774 F.2d 1132, 1138, 227 USPQ 543, 547-48 (Fed. Cir. 1985), is important to our determination, we review the record and lay out the relevant portions of the references in some detail.

A. *The Chinese References*

1. *The Grand Dictionary of Chinese Medicine and Drugs*

(The Grand Dictionary)

The *Grand Dictionary,* published in Hong Kong in 1963 and written in Chinese, is based on ancient Chinese compilations assembled roughly 500 years ago from works of physicians going back 4000-5000 years. Only a portion of the 1963 Chinese text was before the court and is before us on appeal. For purposes of this litigation, that portion was translated into English by Block's translator, Roger Wei-Ming Tsao (Mr. Cao). Mr. Cao is a doctor of Chinese medicine and a bilingual tutor. Block's other expert, Dr. Stephen Wei, a professor of dentistry fluent in Chinese, concurred in that translation. The writings from which the *Grand Dictionary* was compiled are not in evidence nor are any earlier writings.

In a nutshell, the district court relied upon the *Grand Dictionary* because of its discussion of "xiao shi" to which the Grand Dictionary associates the name "niter" and the chemical composition KNO 3and the ability to cure, inter alia, tooth pain. The court's opinion was that this reference teaches the use of xiao shi, which is the same as niter and is therefore the same as potassium nitrate, to cure tooth pain; thus, the teachings of the Rosenthal patent and the *Grand Dictionary* show that the '006 invention would have been obvious.

The following discussion and quotations are part of an attempt to convey the nature of the *Grand Dictionary.* The translated portion of the *Grand Dictionary* is entitled "Niter." The text under the first subheading "Nomenclature" reads: "It was so named because it has the power to consume various stones." Under "Other Names Stated in Classical Medical Books," the text reads "Mang Xiao (Bie-Lu), Bitter Xiao (Zhen-Quan), Flaming Xiao (Tu-Su) . . . and Xiao-Shi . . . ." Thereafter, following "Foreign Names," the *Grand Dictionary* reads: "Salpetrae, Salnitri (in Latin); Niter (in English); and Salpoter (in German)." One page later, "KNO 3" is listed under "Chemical Composition."

The portion upon which Block and the district court rely to show that this substance cures tooth pain is headed "Collective Statements" and reads:

(Ming): Li-Shi-Zhen said: It cures summer infections and the catching of colds. It cures acute enteritis with severe vomiting, exertion through excessive sexual activity, black jaundice, chronic abdominal pain, conjunctivitis, headaches and tooth pain.

The next three or so pages of the *Grand Dictionary* list the ailments that this substance cures. An interesting but not atypical paragraph reads: "For curing the paralysis of the four limbs, leprosy or problems caused by Taoist stone eating." This substance also apparently cures indigestion, lack of energy, typhoid, cataracts, and much, much more. The *Grand Dictionary* compares what appears to

be various forms in which xiao shi is found, and the characteristics of each. An excerpt is:

Pu-Xiao (Na 2SO 4) has the nature of water, tastes salty, and its flavor is cold. It can only descend and cannot ascend. It is Yin within Yin -- that's why it can cleanse the accumulation in the gastrointestinal tract and can expel the San-Jiao devilish fire. Whereas Niter (KNO3) has the nature of fire, tastes bitter and spicy, tastes slightly salty and has a flavor which is very warm, it's [sic] nature is ascending. It is fire within water. That's why it can break the accumulation and disperse hardness, and cure the febrile diseases.

2. Ben Cao Gang Mu

Ben Cao Gang Mu (Ben Cao) is a treatise on Chinese Medicine published in Hong Kong, in Chinese, in 1930, 1954, and 1965, but was originally written by Li-Shi-Zhen who lived during the Ming Dynasty. 3 Like the *Grand Dictionary,* only a portion of the Chinese text *Ben Cao* is in evidence and that portion was translated by Mr. Cao and Dr. Wei for purposes of this litigation. The district court relied upon *Ben Cao* because it discusses "xiao shi," which the translation of *Ben Cao* states is "niter" and associates the ability to cure "tooth pain (Ya Tong or Ya Teng)."

It is important to note, and the district court appeared to accept as fact, that the portion of the *Grand Dictionary* relied upon was compiled during the Ming Dynasty of the 13th to I5th centuries in *Ben Cao Gang Mu* so that the relevant portion of the *Grand Dictionary* is substantially a restatement of *Ben Cao* with some modification by an unidentified author. The court stated that these two references "quote the same Ming Dynasty source as labeling KNO 3for tooth pain."

The *Ben Cao* translation is entitled "Xiao-Shi (Niter)" and refers to the same "Other names" for this substance listed in the *Grand Dictionary.* With respect to the quoted sections above, the *Ben Cao* translation is nearly verbatim. It has this to say about tooth pain:

Da Ming states: It cures summer infections and the catching of colds, acute enteritis with severe vomiting, exertion thru excessive sexual activity and black jaundice, chronic abdominal pain, conjunctivitis, headache and tooth pain (Ya-Tong or Ya Teng).

Hodosh argues that summary judgment was inappropriate; issues of fact as to the meanings of xiao shi and ya tong remain because a skilled dental researcher would surely seek and obtain a complete translation of the *Grand Dictionary* and of the other ancient Chinese references and would read those references carefully. Hodosh also argues that the ancient references should be dismissed because a person skilled in the art would find them incredible and would regard them as a quagmire of medical and dental nonsense. It therefore takes issue with the court's holding quoted below which apparently precluded inquiry into the accuracy of the references by one skilled in the art:

ttacks upon the translation leading up to the prior art reference embodied in the *Grand Dictionary of Chinese Medicine and Drugs,* . . . or upon Chinese medicine as a whole, . . . are not here regarded as particularly pertinent, since they require skill beyond the scope of the "experienced researcher in dental fields . . . ."

Hodosh relies heavily on its expert's, Dr. Shklar's, testimony about the Chinese references: "[T]hey represent in modern terms, materials that are rarely comprehensible and frequently contradictory in their literal terms. The materials are largely seen by contemporary medical scientists as absurd; no serious medical researcher would waste his or her time with them." 4 Hodosh also contests this holding by the district court:

Nor, if it is true that KNO 3alleviates tooth sensitivity, is such reference in the prior art rebutted by the existence of errors in the reference such as, for example, the claim that KNO 3is a cure for "exertion through excessive sexual activity." Whatever the merits of the other aspects of the Chinese references, the fact that they reveal KNO 3to be a cure for ya tong is what is dispositive here. The reference clearly discloses such function of potassium nitrate, albeit in the context of otherwise incredible, and even erroneous descriptions of the compound's quality.

With respect to the specific meaning of xiao shi as used in these references, both Dr. Shklar and Hodosh's other expert, Mr. Yen, a professional translator of Chinese and English languages,

stated that the compiler of the *Grand Dictionary* erred in associating potassium nitrate or niter with xiao shi. Mr. Yen states that he

was not able to render one single precise version because various dictionaries contain different and even conflicting definitions. For example, *Source of Words,* a Chinese language dictionary, published by Commercial Press, Taiwan, which has editions dating back to 1915, defines "Xiao-Shi" as "Mang-Xiao" on page 1255, and under "Mang-Xiao" on page 1770, reference is made that "Mang-Xiao" is "Liu-Suen-Na," and on page 1523 "Liu-Suen-Na" is defined as sodium sulfate ($Na_2SO_4 \cdot 10H_2O$).

Mr. Yen also stated that "Xiao-Shi could be more than one material and that more than one material may be represented by the term 'Xiao-Shi'."

Dr. Shklar concurred:

In my opinion, therefore, the answer to the question: What was "Xiao-Shi," is that it represented many different materials which cannot be identified with certainty.

Thus, these Exhibits did not describe potassium nitrate to one skilled in the art any more than any of the hundreds of salts, ores and oxides that possess some of the enumerated properties.

In addition, Dr. Shklar stated: "It is insufficient to simply state, as the Block translator does, that 'Xiao-Shi' is 'niter,' and then cite a modern dictionary to 'establish' that 'niter' is potassium nitrate." With respect to both the *Grand Dictionary* and *Ben Cao,* he stated that "the translator appears to have inserted the term 'niter' into the text where the phrase 'consumer of stones' actually belongs."

Block's arguments, on the other hand, in part based on the short affidavit by Mr. Wei, substantially follow the

district court's opinion. Block also challenges the competence of Hodosh's experts stating that they "either had no knowledge or training in the Chinese language or Chinese medicine or were unfamiliar with dentistry or medicine generally." Block also emphasizes that the Chinese references correctly disclose many of potassium nitrate's characteristics, like burning with a violet flame, useability for making signal fires and gun powder, and its water solubility; these three properties of xiao shi in the Chinese references definitely confirm, according to Block, that xiao shi is potassium nitrate, KNO 3.

B. *The European Prior Art*

This art is contained in six references and was not relied upon to any significant degree by Block or the district court. Hodosh scarcely mentions it on appeal, instead preferring to show the existence of genuine issues of material fact with respect to the Chinese references. After concluding that using potassium nitrate to cure tooth pain would have been obvious from Rosenthal in view of the Chinese art, the court stated: "Such holding is strengthened by the European prior art which, while ambiguous because of the several conflicting definitions in the term 'niter,' at least suggest to one skilled in the art that potassium nitrate ought to be tried as a cure for tooth pain in general."

Block submitted no affidavits that addressed the substance of the European references. Hodosh's Dr. Shklar, on the other hand, stated why this art, part of the "humors, spirits and Alchemy of the Dark Ages" having whatever medicinal effect they did by virtue of their use of wine, opium, or other narcotic substances, would have been questioned by one skilled in the art. He specifically contends that Block's translation of "nitre" is erroneous: "it is common knowledge that these terms meant sodium carbonate and/or sodium carbonate-sodium bicarbonate mixture. . . ."

To afford a glimpse of the nature of these references, an interesting and typical excerpt, one quoted by the district court, based upon a statement by the long since deceased French surgeon Guy de Chauliac reads that "a mixture of 'cuttlebone, small white sea shells, pumice, burnt stag's horn, *nitre,* alum, rock salt, burnt roots of iris, aristolochia, and reeds' could create an effective dentifrice." (District court's emphasis.) Three of the European references are based on that statement. The district court noted the others:

Additionally, a 1693 treatise by the British Professor of Physics William Salmon states that nitrum "held in the Mouth . . . immediately helps the Toothach, if burnt and used in a Dentifrice, it cleanses and whitens the Teeth." . . . Similarly, a reference work by Hardianus a Mynsicht, translated into English in 1682, describes a mixture, including "nitre" as a "tincture for the toothache." . . . Finally, Pliny the Elder, in his *Historie of the World, The Second Tome,* translated into English in 1601, describes the use of nitre to "easeth the toothach, if the mouth and gums be washed therwith," or if burned, as a dentifrice. [Reference to Exhibits omitted.]

With this description of both the Chinese and European references, and of what they represent as a whole, in hand, we consider the proper application of the *Graham* standards and their effect upon the propriety of summary judgment in this case. *See generally Graham* v. *John Deere Co.,* 383 U.S. 1, 17 [148 USPQ 459, 467] (1966); *Panduit Corp.* v. *Dennison*

Manufacturing Co., 774 F.2d 1082, 227 USPQ 337 (Fed. Cir. 1985).

OPINION

A. *Summary Judgment*

Summary judgment, in patent as in other cases, is appropriate where there is no genuine issue of material fact, and the movant is entitled to judgment as a matter of law. *See Molinaro* v. *Fannon/Courier Corp.* 745 F.2d 651, 653-54, 223 USPQ 706, 707 (Fed. Cir. 1984). The movant bears the burden of demonstrating the absence of all

genuine issues of material fact, and the district court must view the evidence in a light most favorable to the nonmoving party and draw all reasonable inferences in its favor. *See United States* v. *Diebold, Inc.,* 369 U.S. 654, 655 (1962); *Palumbo* v. *Don-Joy Co.,* 762 F.2d 969, 973, 226 USPQ 5, 7 (Fed. Cir. 1985). The party opposing summary judgment must show an evidentiary conflict on the record; mere denials or conclusory statements are not sufficient. *Barmag Barmer Maschinenfabrik AG* v. *Murata Machinery, Ltd.,* 731 F.2d 831, 836, 221 USPQ 561, 564 (Fed. Cir. 1984). Summary judgment is authorized where it is quite clear what the truth is. *Sartor* v. *Arkansas Natural Gas Corp.,* 321 U.S. 620, 627 (1944).

B. *The Issues Below*

The decision and opinion of the district court granting summary judgment dealt with two issues: the first was whether the '006 patent is invalid as anticipated under §102(b), the court holding it is not; and the second was whether the '006 patent is invalid for obviousness under §103, the court holding that it is. Hodosh of course appeals the summary judgment with respect to only the issue on which it lost -- obviousness and Block has not appealed. Because we are remanding for trial, however, we will comment briefly on anticipation to make it clear that we deem that question to have been conclusively disposed of in this case and because it is closely related to the obviousness issue.

1. *Anticipation, §102(b)*

We agree entirely with the district court's holding that the '006 patent is not invalid as anticipated because there is no issue of fact that none of the prior art references discloses every element of the claimed invention. This issue was, therefore, appropriately and properly disposed of by summary judgment.

We do not agree, however, with some of the district court's remarks about anticipation, in particular, that the unavailability of the Chinese references and whether one skilled in the art could locate them with "reasonable diligence" bears on whether those references anticipate the claimed subject matter. Whether a reference is available as prior art and whether it anticipates (i.e., contains every claimed element) are separate questions. Moreover, the district court's determination that the references are unavailable for §102 purposes seems to be inconsistent with the approach subsequently taken by the district court in determining obviousness. The court later used these same references to support its holding that the claimed subject matter would have been obvious at the time the invention was made to one of ordinary skill in the art.

2. *Obviousness, §103*

[1] Questions of material fact remain with respect to the meaning of various terms used in the Chinese and European references and we therefore hold that summary judgment on the ground of obviousness of the claimed invention was improper.

The district court's statement that ya tong means tooth hypersensitivity as well as tooth pain is the resolution of a head-on factual controversy. The court improperly drew the inference against Hodosh, the nonmoving party, that a statement about ya tong made to the German Patent Office by Dr. Hodosh's German patent agent was made with knowledge of the Chinese references. The statement in question occurred seven years after the '006 patent issued in connection with Dr. Hodosh's counterpart German application. The statement was: "The supersensitivity of dentine has been known for a long time and can be traced back 4000 years to the Chinese where it was known as 'Ya Tong'." Hodosh in this suit disclaims this statement urging that it was factual error.

There is no evidence that the above statement was based on the Chinese references or that Dr. Hodosh conveyed this information to the German patent agent. The important fact question as to the meaning of ya tong cannot be overcome simply by styling this statement an admission binding on Hodosh. Hodosh is entitled, as Block essentially concedes, to rebut the statement with evidence to the contrary. Hodosh will have that chance at trial. Nor does the statement in the affidavit of Block's expert, Dr. Wei, that ya tong means tooth hypersensitivity eliminate the presence of the question of the meaning of ya tong. As the Supreme Court long ago observed,

"Experience

has shown that opposite opinions of persons professing to be experts, may be obtained to any amount. . . ." *Winans* v. *New York and Erie Railroad Co.*, 62 U.S. 88 (1859). The substance of Dr. Skhlar's affidavit on behalf of Hodosh goes far beyond merely denying that ya tong means tooth hypersensitivity and thus is more than adequate to show an evidentiary conflict on the record with respect to this crucial point, thus precluding summary judgment. *Cf. Union Carbide Corp.* v. *American Can* Co., 724 F.2d 1567, 1571, 220 USPQ 584, 587-88 (Fed. Cir. 1984). Furthermore, a genuine issue of material fact exists with respect to the meaning of the terms nitre, nitrum, and nitri as used in the European references. Dr. Sklhar's affidavit is more than adequate to withstand the challenge of this summary judgment motion. A reasonable inference that these terms are sodium, as opposed to potassium, compounds is permissible; Hodosh has shown an evidentiary conflict on the record. The European references, Dr. Sklhar explained in his affidavit, are based on the 77 A.D. writings of Pliny The Elder, who understood these terms to mean "sodium carbonate and/or a sodium carbonate-sodium bicarbonate mixture."

The obviousness determination here, given the existence of genuine material issues of fact with respect to the meanings of terms used in these references, is not suitably disposed of by summary judgment under the rules pertaining thereto. *See generally Palumbo,* supra, and *Lemelson* v. *TRW, Inc.*, 760 F.2d 1254, 1260-61, 225 USPQ 697, 700-01 (Fed. Cir. 1985). The fact issues herein must be resolved by trial in which the conflicting views of the experts will be subject to the refining fire of cross examination, a more effective means of arriving at the legal conclusion of obviousness vel non than perusal of ex parte affidavits and declarations of partisan experts lobbed at each other from opposing trenches.

We observe, for the benefit of the trial court, that we are totally unimpressed by Block's forensic device of comparing the Rosenthal prior art toothpaste formula and the Hodosh toothpaste example in parallel columns and then asserting, as though it were filled with significant meaning, that the "only difference is the use of potassium nitrate in place of strontium chloride," or that "the Hodosh patent merely substitutes potassium nitrate for strontium chloride." This device was pushed to the limit in oral argument by pointing out that the Hodosh toothpaste has the *same* formula, *except* for the active desensitizing ingredient, down to the last decimal point. This argument is meaningless on the obviousness issue. "Sensodyne" and apparently other desensitizing toothpaste formulae being well known as commercial products, it is entirely clear that Dr. Hodosh's invention was the discovery of an apparently superior *desensitizing agent* and he never thought it was a toothpaste formula. He made that invention even if it should later be decided that it was known to the Chinese. It is apparent that Hodosh's patent solicitor merely adopted the prior art Rosenthal toothpaste base formula as a convenient example to illustrate the kind of a paste in which the Hodosh desensitizer might be used, which was within his right. The similarities -- indeed, identity -- of the paste bases is irrelevant in considering the issue of the unobviousness of the desensitizer. The Rosenthal patent, cited as prior art by Hodosh in his patent specification, was the jumping-off place for the description of his discovery. Hodosh does not claim to have been the first inventor of a desensitizing toothpaste; he claims to have improved it. The issue for trial is whether his improvement would have been obvious. 5

C. Secondary Considerations

The district court refused on the motion for summary judgment to consider the evidence of secondary considerations. After acknowledging its existence and the arguments based on it, it stated:

However, the court continues to find that the Hodosh patent is invalid on grounds of obviousness; these secondary

considerations stem not from the novelty or inventiveness engendered by substituting potassium nitrate in an already existing formula, but from a lack of knowledge on the part of those in the field of the references here cited. That lack is here overcome by the presumption of omniscience discussed, *supra,* a rule of law by which the court is bound, whatever its merits.

[2] That secondary considerations are not considered unless there is evidence that those in the industry knew of the prior art is a non sequitur. Evidence of secondary considerations is considered independently of what any real person *knows* about the prior art. These considerations are *objective* criteria of obviousness that help illuminate the subjective determination involved in the hypothesis used to draw the legal conclusion of obviousness based upon the first three factual inquiries delineated in *Graham.* Thus, to require that actual inventors in the field have the omniscience of the hypothetical person in the art is not only contrary to case law, *see Kimberly-Clark* v. *Johnson & Johnson,* 745 F.2d 1437, 223 USPQ 603 (Fed. Cir. 1984), but eliminates a useful tool for trial judges faced with a nonobviousness determination.

The secondary consideration evidence of record and the additional evidence likely to be submitted at trial must be considered in the obviousness determination. *See generally Fromson* v. *Advance Offset Plate, Inc.,* 755 F.2d 1549, 1557, 225 USPQ 26, 32 (Fed. Cir. 1985).

Conclusion

The grant of summary judgment of invalidity is *reversed* and the case is *remanded* for trial in accordance with this opinion.

REVERSED AND REMANDED

Footnotes

Footnote 1. A certificate of reexamination confirming the patentability of claims 1-6 of the '006 patent was issued June 21, 1983, as a result of Hodosh's request for reexamination in 1982. Only one of the prior art references involved here, the Rosenthal patent, infra, was considered in the reexamination.

Footnote 2. Block also initiated regulatory proceedings designed to delay or prevent Richardson-Vicks' marketing of "Denquel." Block, having allegedly failed to comply with Food and Drug Administration (FDA) procedures before marketing "Promise" and "Sensodyne-F" in competitive response to Richardson-Vicks' introduction of "Denquel," is currently defending itself in forfeiture proceedings initiated by the FDA.

Footnote 3. The Ming Dynasty (1368-1644 AD) was marked by the restoration of traditional institutions in China and the development of the arts, especially in porcelain, textiles, and painting.

Footnote 4. Dr. Shklar is the Charles A. Brackett Professor of Oral Pathology at the Harvard School of Dental Medicine, and is an acclaimed expert in dentistry. He is also an expert on the history of dentistry and holds membership in the American Academy of the History of Dentistry.

Footnote 5. Our comments on the district court's obviousness determination generally include the following tenets of patent law that must be adhered to when applying §103: (1) the claimed invention must be considered as a whole (35 USC 103; *see, e.g., Jones* v. *Hardy,* 727 F.2d 1524, 1529, 220 USPQ 1021, 1024 (Fed. Cir. 1984) (though the difference between claimed invention and prior art may seem slight, it may also have been the key to advancement of the art)); (2) the references must be considered as a whole and suggest the desirability and thus the obviousness of making the combination *(see, e.g., Lindemann Maschinenfabrik GmbH* v. *American Hoist and Derrick Co.,* 730 F.2d 1452, 1462, 221 USPQ 481, 488 (Fed. Cir. 1984); (3) the references must be viewed without the benefit of hindsight vision afforded by the claimed invention *(e.g., W.L. Gore & Associates, Inc.* v. *Garlock, Inc.,* 721 F.2d 1540, 1553, 220 USPQ 303, 313 (Fed. Cir. 1983)); (4) "ought to be tried" is not the standard with

which obviousness is determined *(Jones,* supra, 727 F.2d at 1530, 220 USPQ at 1026); and (5) the presumption of validity remains constant and intact throughout litigation (35 USC 285; *e.g., American Hoist & Derrick Co. v. Sowa & Sons, Inc.,* 725 F.2d 1350, 1359-60, 220 USPQ 763, 770 (Fed. Cir. 1984)).

- End of Case -

Intellectual Property Library ISSN 1526-8535

FULL TEXT OF CASES (USPQ2D)
All Other Cases

In re Fine (CA FC) 5 USPQ2d 1596 In re Fine

U.S. Court of Appeals Federal Circuit
5 USPQ2d 1596

Decided January 26, 1988
No. 87-1319

Headnotes

PATENTS

1. Patentability/Validity -- Obviousness -- Evidence of (§ 115.0903)

Patent and Trademark Office improperly rejected claimed invention for obviousness since nothing in cited references, either alone or in combination, suggests or teaches claimed invention, since there is consequently no support for PTO's conclusion that substitution of one type of detector for another in prior art system, resulting in claimed invention, would have been obvious, and since PTO therefore failed to satisfy its burden of establishing prima facie case of obviousness by showing some objective teaching or generally available knowledge that would lead one skilled in art to combine teachings of existing references.

2. Patentability/Validity -- Obviousness -- In general (§ 115.0901)

Obviousness is tested by what combined teachings of prior art references would have suggested to those of ordinary skill in art, not by whether particular combination of elements from such references might have been "obvious to try."

3. Patentability/Validity -- Obviousness -- Evidence of (§ 115.0903)

Patent and Trademark Office erred, in rejecting as obvious system for detecting and measuring minute quantities of nitrogen compounds, by failing to recognize that appealed claims can be distinguished over combination of prior art references, in view of evidence demonstrating that prior art does not teach claimed temperature range, despite some overlap of preferred temperature ranges for claimed invention and prior art, since purposes of preferred temperature ranges are different and overlap is mere happenstance.

4. Patentability/Validity -- Obviousness -- In general (§ 115.0901)

Dependent claims are non-obvious under 35 USC 103 if claims from which they depend are non-obvious.

Case History and Disposition:

Appeal from the U.S. Patent and Trademark Office Board of Patent Appeals and Interferences.

Application for patent by David H. Fine, Serial No. 512,374. From decision of Board of Patent Appeals and Interferences affirming rejection of application, applicant appeals. Reversed; Smith, circuit judge, dissenting with opinion.

Attorneys:

Morris Relson and Darby & Darby, New York, N.Y., (Beverly B. Goodwin with them on the brief) for appellant.

Lee E. Barrett, associate solicitor, Arlington, Va., (Joseph F. Nakamura, solicitor, and Fred E. McKelvey, deputy solicitor, with him on the brief) for appellee.

Judge:

Before Friedman, Smith, and Mayer, circuit judges.

Opinion Text

Opinion By:

Mayer, J.

David H. Fine appeals from a decision of the Board of Patent Appeals and Interferences of the United States Patent and Trademark Office (Board) affirming the rejection of certain claims of his application, Serial No. 512,374, and concluding that his invention would have been obvious to one of ordinary skill in the art and was therefore

unpatentable under 35 U.S.C. §103. We reverse.

Background

A. *The Invention*.

The invention claimed is a system for detecting and measuring minute quantities of nitrogen compounds. According to Fine, the system has the ability to detect the presence of nitrogen compounds in quantities as minute as one part in one billion, and is an effective means to detect drugs and explosives, which emanate nitrogen compound vapors even when they are concealed in luggage and closed containers.

The claimed invention has three major components: (1) a gas chromatograph which separates a gaseous sample into its constituent parts; (2) a converter which converts the nitrogen compound effluent output of the chromatograph into nitric oxide in a hot, oxygen-rich environment; and (3) a detector for measuring the level of nitric oxide. The claimed invention's sensitivity is achieved by combining nitric oxide with ozone to produce nitrogen dioxide which concurrently causes a detectable luminescence. The luminescence, which is measured by a visual detector, shows the level of nitric oxide which in turn is a measure of nitrogen compounds found in the sample.

The appealed claims were rejected by the Patent and Trademark Office (PTO) under 35 U.S.C. §103. Claims 60, 63, 77 and 80 were rejected as unpatentable over Eads, Patent No. 3,650,696 (Eads) in view of Warnick, et al., Patent No. 3,746,513 (Warnick). Claims 62, 68, 69, 79, 85 and 86 were rejected as unpatentable over Eads and Warnick in view of Glass, et al., Patent No. 3,207,585 (Glass).

B. *The Prior Art*.

1. *Eads Patent*.

Eads discloses a method for separating, identifying and quantitatively monitoring sulfur compounds. The Eads system is used primarily in "air pollution control work in the scientific characterization of odors from sulfur compounds."

The problem addressed by Eads is the tendency of sulfur compounds "to adhere to or react with the surface materials of the sampling and analytical equipment, and/or react with the liquid or gaseous materials in the equipment." Because of this, the accura

cy of measurement is impaired. To solve the problem, the Eads system collects an air sample containing sulfur compounds in a sulfur-free methanol solution. The liquid is inserted into a gas chromatograph which separates the various sulfur compounds. The compounds are next sent through a pyrolysis furnace where they are oxidized to form sulfur dioxide. Finally, the sulfur dioxide passes through a measuring device called a microcoulometer which uses titration cells to calculate the concentration of sulfur compounds in the sample.

2. *Warnick Patent*.

Warnick is directed to a means for detecting the quantity of pollutants in the atmosphere. By measuring the chemiluminescence of the reaction between nitric oxide and ozone, the Warnick device can detect the concentration of nitric oxide in a sample gaseous mixture.

Warnick calls for "continuously flowing" a sample gaseous mixture and a reactant containing ozone into a reaction chamber. The chemiluminescence from the resulting reaction is transmitted through a light-transmitting element to produce continuous readouts of the total amount of nitric oxide present in the sample.

3. Glass Patent.

The invention disclosed in Glass is a device for "completely burning a measured amount of a substance and analyzing the combustion products." A fixed amount of a liquid petroleum sample and oxygen are supplied to a flame. The flame is then spark-ignited, causing the sample to burn. The resulting combustion products are then collected and measured, and from this measurement the hydrogen concentration in the sample is computed.

C. *The Rejection .*

The Examiner rejected claims 60, 63, 77 and 80 because "substitution of the [nitric oxide] detector of Warnick for the sulfur detector of Eads would be an obvious consideration if interested in nitrogen compounds, and would yield the claimed invention." He further asserted that "Eads teaches the [claimed] combination of chromatograph, combustion, and detection, in that order. . . . Substitution of detectors to measure any component of interest is well within the skill of the art." In rejecting claims 62, 68, 69, 79, 85 and 86, the Examiner said, "Glass et al. teach a flame conversion means followed by a detector, and substitution of the flame conversion means of Glass et al. for the furnace of Eads would be an obvious equivalent and would yield the claimed invention." The Board affirmed the Examiner's rejection.

Discussion

A. *Standard of Review .*

Obviousness under 35 U.S.C. §103 is " 'a legal conclusion based on factual evidence.' " *Stratoflex, Inc. v. Aeroquip Corp .*, 713 F.2d 1530, F.2d 1530, 1535, 218 USPQ 871, 876 (Fed. Cir. 1983) (quoting *Stevenson v. Int'l Trade Comm'n* , 612 F.2d 546, 549, 204 USPQ 276, 279 (CCPA 1979)). Therefore, an obviousness determination is not reviewed under the clearly erroneous standard applicable to fact findings, *Raytheon Co. v. Roper Corp .*, 724 F.2d 951, 956, 220 USPQ 592, 596 (Fed. Cir. 1983); it is "reviewed for correctness or error as a matter of law." *In re De Blauwe* , 736 F.2d 699, 703, 222 USPQ 191, 195 (Fed. Cir. 1984).

To reach a proper conclusion under §103, the decisionmaker must step backward in time and into the shoes worn by [a person having ordinary skill in the art] when the invention was unknown and just before it was made. In light of *all* the evidence, the decisionmaker must then determine whether . . . the claimed invention as a whole would have been obvious at *that* time to *that* person. 35 U.S.C. §103. The answer to that question partakes more of the nature of law than of fact, for it is an ultimate conclusion based on a foundation formed of all the probative facts.

Panduit Corp. v. Dennison Mfg. Co ., 810 F.2d 1561, 1566, 1 USPQ2d 1593, 1595-96 (Fed. Cir. 1987).

B. *Prima Facie Obviousness .*

Fine says the PTO has not established a *prima facie* case of obviousness. He contends the references applied by the Board and Examiner were improperly combined, using hindsight reconstruction, without evidence to support the combination and in the face of contrary teachings in the prior art. He argues that the appealed claims were rejected because the PTO thought it would have been "obvious to try" the claimed invention, an unacceptable basis for rejection.

[1] We agree. The PTO has the burden under section 103 to establish a *prima facie* case of obviousness. *See In re Piasecki* , 745 F.2d 1468, 1471-72, 223 USPQ 785, 787-87 (Fed. Cir. 1984). It can satisfy this burden only by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the references. *In re Lalu* , 747 F.2d 703, 705, 223 USPQ 1257, 1258 (Fed. Cir. 1984); *see also Ashland Oil, Inc. v. Delta Resins & Refractories, Inc .*,

776 F.2d 281, 297 n.24, 227 USPQ 657 , 667 n.24 (Fed. Cir. 1985); *ACS Hosp. Sys., Inc. v. Montefiore Hosp .*, 732 F.2d 1572, 1577, 221 USPQ 929, 933 (Fed. Cir. 1984). This it has not done. The Board points to nothing in

the cited references, either alone or in combination, suggesting or teaching Fine's invention.
The primary basis for the Board's affirmance of the Examiner's rejection was that it would have been obvious to substitute the Warnick nitric oxide detector for the Eads sulfur dioxide detector in the Eads system. The Board reiterated the Examiner's bald assertion that "substitution of one type of detector for another in the system of Eads would have been within the skill of the art," but neither of them offered any support for or explanation of this conclusion.
Eads is limited to the analysis of sulfur compounds. The particular problem addressed there is the difficulty of obtaining precise measurements of sulfur compounds because of the tendency of sulfur dioxide to adhere to or react with the sampling analytic equipment or the liquid or gaseous materials in the equipment. It solves this problem by suggesting that the gaseous sample containing sulfur compounds be absorbed into sulfur-free methanol and then inserted into a gas chromatograph to separate the sulfur compounds.
There is no suggestion in Eads, which focuses on the unique difficulties inherent in the measurement of sulfur, to use that arrangement to detect nitrogen compounds. In fact, Eads says that the presence of nitrogen is undesirable because the concentration of the titration cell components in the sulfur detector is adversely affected by substantial amounts of nitrogen compounds in the sample. So, instead of suggesting that the system be used to detect nitrogen compounds, Eads deliberately seeks to avoid them; it warns against rather than teaches Fine's invention. *See W. L. Gore & Assoc. v. Garlock, Inc* ., 721 F.2d 1540, 1550, 220 USPQ 303, 311 (Fed. Cir. 1983) (error to find obviousness where references "diverge from and teach away from the invention at hand"). In the face of this, one skilled in the art would not be expected to combine a nitrogen-related detector with the Eads system. Accordingly, there is no suggestion to combine Eads and Warnick.
Likewise, the teachings of Warnick are inconsistent with the claimed invention, to some extent. The Warnick claims are directed to a gas stream from engine exhaust "continuously flowing the gaseous mixtures into the reaction chamber" to obtain "continuous readouts" of the amount of nitric oxide in the sample. The other words, it contemplates measuring the total amount of nitric oxide in a continuously flowing gaseous mixture of unseparated nitrogen constituents. By contrast, in Fine each nitrogen compound constituent of the gaseous sample is retained in the Chromatograph for an individual time period so that each exists in discrete, time-separated pulses. * By this process, each constituent may be both identified by its position in time sequence, and measured. The claimed system, therefore, diverges from Warnick and teaches advantages not appreciated or contemplated by it.
Because neither Warnick nor Eads, alone or in combination, suggests the claimed invention, the Board erred in affirming the Examiner's conclusion that it would have been obvious to substitute the Warnick nitric oxide detector for the Eads sulfur dioxide detector in the Eads system. *ACS Hosp. Sys* ., 732 F.2d at 1575-77, 221 USPQ at 931-33. The Eads and Warnick references disclose, at most, that one skilled in the art might find it obvious to try the claimed invention. But whether a particular combination might be "obvious to try" is not a legitimate test of patentability. *In re Geiger* , 815 F.2d 868, 688, 2 USPQ2d 1276, 1278 (Fed. Cir. 1987); *In re Goodwin* , 576 F.2d 375, 377, 198 USPQ 1, 3 (CCPA 1978).
[2] Obviousness is tested by "what the combined teachings of the references would have suggested to those of ordinary skill in the art." *In re Keller* , 642 F.2d 413, 425, 208 USPQ 871, 881 (CCPA 1981). But it "cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination." *ACS Hosp. Sys* ., 732 F.2d at 1577, 221 USPQ at 933. And "teachings of references can be combined *only* if there is some suggestion or incentive to do so." *Id* . Here, the prior art contains none.
Instead, the Examiner relies on hindsight in reaching his obviousness determination.

But this court has said, "To imbue one of ordinary skill in the art with knowledge of the invention in suit, when no prior art reference or references of record convey or suggest that knowledge, is to fall victim to the insidious effect

of a hindsight syndrome wherein that which only the inventor taught is used against its teacher." *W. L. Gore* , 721 F.2d at 1553, 220 USPQ at 312-13. It is essential that "the decisionmaker forget what he or she has been taught at trial about the claimed invention and cast the mind back to the time the invention was made . . . to occupy the mind of one skilled in the art who is presented only with the references, and who is normally guided by the then-accepted wisdom in the art." *Id* . One cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention.

C. *Advantage Not Appreciated by the Prior Art* .

[3] The Board erred not only in improperly combining the Eads and Warnick references but also in failing to appreciate that the appealed claims can be distinguished over that combination. A material limitation of the claimed system is that the conversion to nitric oxide occur in the range of 600°C to 1700°C. The purpose of this limitation is to prevent nitrogen from other sources, such as the air, from being converted to nitric oxide and thereby distorting the measurement of nitric oxide derived from the nitrogen compounds of the sample.
The claimed nitric oxide conversion temperature is not disclosed in Warnick. Although Eads describes a preferred temperature of 675°C to 725°C, the purpose of this range is different from that of Fine. Eads requires the 675°C to 725°C range because it affords a temperature low enough to avoid formation of unwanted sulfur trioxide, yet high enough to avoid formation of unwanted sulfides. Fine's temperature range, in contrast, does not seek to avoid the formation of sulfur compounds or even nitrogen compounds. It enables the system to break down the nitrogen compounds of the sample while avoiding the destruction of background nitrogen gas. There is a partial overlap, of course, but this is mere happenstance. Because the purposes of the two temperature ranges are entirely unrelated, Eads does not teach use of the claimed range. *See In re Geiger* , 815 F.2d at 688, 2 USPQ2d at 1278. The Board erred by concluding otherwise.

D. *Unexpected Results* .

Because we reverse for failure to establish a *prima facie* case of obviousness, we need not reach Fine's contention that the Board failed to accord proper weight to the objective evidence of unexpected superior results. *Id* .

E. *The "Flame" Claims* .

[4] Claims 62, 68, 69, 79, 85 and 86 relate to the oxygen-rich flame conversion means of the claimed invention. These "flame" claims depend from either apparatus claim 60 or method claim 77. Dependent claims are nonobvious under section 103 if the independent claims from which they depend are nonobvious. *Hartness Int'l, Inc. v. Simplimatic Eng'g Co* ., 819 F.2d 1100, 1108, 2 USPQ2d 1826, 1831 (Fed. Cir. 1987); *In re Abele* , 684 F.2d 902, 910, 214 USPQ 682, 689 (CCPA 1982); *see also In re Sernaker* , 702 F.2d 989, 991, 217 USPQ 1, 3 (Fed. Cir. 1983). In view of our conclusion that claims 60 and 77 are nonobvious, the dependent "flame" claims are also patentable.

Conclusion

The Board's decision affirming the Examiner's rejection of claims 60, 62, 63, 68, 69, 77, 79, 80, 85 and 86 of Fine's application as unpatentable over the prior art under 35 U.S.C. §103 is *REVERSED* .

Footnotes

Footnote *. The Solicitor argues that the contents of Attachment C of Fine's brief were not before the Board and may not properly be considered here. However, we need not rely on Attachment C. It is merely illustrative of the qualitative separation of nitrogen compounds which occurs in Fine's system. The fact that the various constituents exit at discrete intervals is shown by the specification which was before the Board and which may appropriately be

considered on appeal. *See, e.g., Astra-Sjuco, A.B. v. United States Int'l Trade Comm'n* , 629 F.2d 682, 686, 207 USPQ 1, 5 (CCPA 1980) (claims must be construed in light of specification).

Dissenting Opinion Text

Dissent By:

Smith, circuit judge, dissenting.

I respectfully dissent. I am of the firm belief that the prior art references, relied upon by the PTO to establish its prima facie case of obviousness, in combination teach and suggest Fine's invention to one skilled in the art. Also, I firmly believe that Fine failed to rebut the PTO's prima facie case. On this basis, I would affirm the board's determination sustaining the examiner's rejection, pursuant to 35 U.S.C. §103, of Fine's claims on appeal before this court.

- End of Case -

